EXHIBIT A

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

INVACARE CORP.

AUG 29 2011

RECEIVED

TO: GERALD B BLOUCH
C/O INVACARE CORPORATION
ONE INVACARE WAY, PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

You are hereby summoned and required to serve a copy of your answer to the complaint upon the plaintiff's attorney, or upon the plaintiff, if he has no attorney of record, within **TWENTY-EIGHT (28) DAYS** after service of this summons on you, exclusive of the day you receive it. Your answer must **ALSO** be filed with this Court within three (3) days after you serve, (delivered or by mail), a copy of your answer on the plaintiff's attorney.

If you fail to appear and defend, judgment by default will be rendered against you for the relief demanded in the complaint.

RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: AARON MALACHI MIXON III
C/O INVACARECORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: JOSEPH B RICHEY II
C/O INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: MICHAEL F DELANEY
C/O INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: DAN T MOORE III
C/O INVACARE CORPOARTION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: WILLIAM M WEBER
C/O INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: K. Grills
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

RECEIVED
AUG 29 2011
MAL MIXON

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: JAMES L JONES JR
C/O INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: C MARTIN HARRIS
C/O INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

A copy of the complaint is attached hereto. The name and address of the plaintiff's attorney is:

JAMES B ROSENTHAL
COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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RON NABAKOWSKI
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LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

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INVACARE CORP.

AUG 29 2011

RECEIVED

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: DALE C LAPORTE
C/O INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

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LANSING, MI 48933

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: K. Gillis
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: CHARLES S ROBB
C/O INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

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LANSING POLICE & FIRE RETIREMENT SYSTEM (CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

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COHEN, ROSENTHAL & KRAMER LLP
700 W ST.CLAIR AVE, STE 400
CLEVELAND, OH 44113

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: K. Grills
Deputy Clerk

LORAIN COUNTY COURT OF COMMON PLEAS

LORAIN COUNTY JUSTICE CENTER
225 COURT STREET
ELYRIA, OHIO 44035

LANSING POLICE & FIRE RETIREMENT SYSTEM
(CITY OF)
124 WEST MICHIGAN AVE #5
LANSING, MI 48933

CASE NO. 11CV173235

VS.

TO: INVACARE CORPORATION
ONE INVACARE WAY PO BOX 4028
ELYRIA, OH 44036

SUMMONS ON COMPLAINT

You have been named defendant in a complaint filed in Lorain County Court of Common Pleas by plaintiff(s):

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LANSING, MI 48933

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RON NABAKOWSKI
CLERK OF COURTS OF COMMON PLEAS
LORAIN COUNTY, OHIO

8/26/2011

BY: _____
Deputy Clerk

IN THE COURT OF COMMON PLEAS
LORAIN COUNTY, OHIO

CITY OF LANSING POLICE AND FIRE RETIREMENT SYSTEM, Derivatively On Behalf of INVACARE CORPORATION
124 West Michigan Avenue, #5
Lansing, Michigan 48933,

Plaintiff,

v.

GERALD B. BLOUCH
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

AARON MALACHI MIXON III
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

JOSEPH B. RICHEY II
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

MICHAEL F. DELANEY
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

C.A. No. 11CV173235

JUDGE JUDGE MARK A. BETLESKI

VERIFIED DERIVATIVE COMPLAINT

[Jury Demand Endorsed Hereon]

FILED
LORAIN COUNTY
2011 AUG 23 P 4:14
CLERK OF COMMON PLEAS
RON KARAKOWSKI

DAN T. MOORE III
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

WILLIAM M. WEBER
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

JAMES L. JONES, JR.
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

C. MARTIN HARRIS
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

DALE C. LAPORTE
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

and

CHARLES S. ROBB
c/o Invacare Corporation
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

Defendants,

and

INVACARE CORPORATION
One Invacare Way, P.O. Box 4028
Elyria, Ohio 44036,

Nominal Defendant.

VERIFIED DERIVATIVE COMPLAINT

Plaintiff, City of Lansing Police and Fire Retirement System ("Plaintiff"), by its attorneys, brings this action derivatively on behalf of Invacare Corporation ("Invacare" or the "Company"), and makes the following allegations against the members of Invacare's Board of Directors (the "Board"). The allegations of the Complaint are based on the personal knowledge of Plaintiff as to itself and its own acts, and upon information and belief as to all other matters, based upon the investigation conducted by and through its attorneys, which included, among other things, a review of United States Securities and Exchange Commission ("SEC") filings, news reports, press releases, other publicly available documents concerning Invacare, and interviews with former Invacare employees.

SUMMARY OF THE ACTION

1. This is a stockholder derivative action brought on behalf of Invacare by one of its shareholders against Invacare's Board for breach of fiduciary duty for its utter failure over a period of many years (at least over a decade) to adequately monitor the Company's safety and compliance practices and procedures, causing the Company to be exposed to serious harm and liability.

2. Invacare bills itself as one of the world's leading manufacturers and distributors of home and long-term care medical products. Among its key products are beds used in long term care, including electric/automated adjustable beds, bariatric beds and other specialty beds.

This action relates, in significant part, to safety and safety documentation and incident tracking issues at Invacare, most recently with respect to these bed products. These issues have been effectively disregarded by the Defendants and the Company for years, and even after the United States Food and Drug Administration ("FDA") identified extremely troubling safety shortfalls and systemic deficiencies in the Company's procedures and practices to record, track, evaluate and correct safety issues.

3. As set forth herein, Defendants have exposed Invacare to significant harm by participating, encouraging and /or allowing a highly improper business environment, including improper, materially deficient and/or non-existent policies, practices and procedures, including those involving safety and complaint reporting and documentation systems for the Company's medical products. This environment has prevailed (and apparently continues to do so) at Invacare and permeates its business culture, starting with senior management and the Board. The Defendants knew or were recklessly ignorant of these problems, as these have been serious similar recurring issues for over a decade.

4. In August 2010, the FDA conducted an inspection of Invacare's Sanford, Florida plant, one of the Company's self-described four "major" manufacturing facilities. As a result of that inspection, which lasted a number of weeks, the FDA found significant safety, recordkeeping and compliance issues, including among others:

- Improper responses to "recurring complaints relating to potential sparks/fires associated with the beds."
- Among the more serious complaints, reports of control systems shooting sparks, beds catching fire, and patients getting trapped between the mattress and the rail -- two such incidents reportedly resulting in death.
- A finding that the Company's beds were "adulterated" because the methods or facilities used to manufacture them were "not in conformity with the Current Good Manufacturing Practice."

- A failure to establish and maintain adequate procedures to analyze processes to identify products that do not conform to FDA regulations and guidelines.

- A finding that Invacare beds were "misbranded" under federal law, in that Invacare had failed or refused to furnish material or information respecting the beds as required by federal law and regulations.[1]

- A failure to submit complaints concerning entrapment of patients in Invacare beds, as required to the FDA.

5. As set forth herein, the problems relating to the Company's beds and other products, as well as critical record keeping and complaint handling procedures and practices, and the Company's failure to adequately document and track these issues in compliance with federal law and regulations date back over a decade. These issues, and their persistence for years on end, indicate an alarmingly similar and ongoing pattern of conduct both in terms of the FDA inspection, safety and documentation issues plaguing the Company. The seriousness and persistence of these issues, among other things, also highlight the consistently antagonistic and counterproductive treatment of these and similar issues by the Company and its leadership, even after they became public.

6. Plaintiff's counsel's investigation included, among other things, interviews with former Invacare employees, and a review of the Company's prior dealings with the FDA (including, *inter alia*, similar warning letters sent by the FDA to Invacare in May 1996, August 1998, and August 2003), and indicates that the same type of ongoing issues with the Company's

[1] This included a failure to report to the FDA within 30 calendar days after becoming aware of information that reasonably suggested that a device marketed by Invacare had malfunctioned and this device or a similar device marketed by the Company "would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2)."

safety, record-keeping and inadequate internal controls reaches back at least as far back as 1996 (if not earlier).

7. In 1996, the FDA reportedly issued stark warnings to the Company concerning its failure to comply with Good Manufacturing Practices (GMP) and Medical Device Reporting (MDR) principles, some of the same principles and guidelines implicated by Invacare's late 2010 infractions. The 1996 warnings (which also included a Warning Letter involving Invacare's Sanford facility) appear to be remarkably similar to the FDA's findings and warnings in late 2010.

8. An August, 1997 article appearing in *HighBeam Research* (and contained on the website Highbeamresearch.com) entitled *Invacare, FDA Dispute Intent of GMPs, MDRs (Good Manufacturing Practices, Medical Device Reporting)* reported that the FDA had followed a January, 1996 inspection with a nine-page May 1996 Warning Letter which showed that "a variety of record-keeping problems haunt Invacare in its dealings with the FDA and that the agency was unswayed by the firm's attempts to defend its practices with its own interpretations of [Good Manufacturing Practices] and Medical Device Reporting (MDR)."

9. On August 20, 1998, the FDA sent Invacare a warning letter (the "1998 Warning Letter", a copy which is attached to this complaint as Exhibit 1) following an inspection of the Sanford, Florida facility in July 1998. The FDA investigator "collected information that revealed serious regulatory problems involving electric patient beds, lift out chairs, and adjustable, automatic air mattresses." Again, the 1998 Warning Letter indicates violations substantially similar to those described in the most recent Warning Letter, including adulterated devices, and failure to validate and document processes and quality assurance tests.

10. A September 1, 2002 news article in the *Cleveland Plain Dealer* entitled "*Fires, deaths linked to Invacare wheelchairs*" recounted wiring and battery-charging defects which caused fatal fires in Invacare's wheelchair products, a recall covering hundreds of thousands of Invacare wheelchairs manufactured between 1985 and 2000, and the Company's violation of FDA requirements by failing to report at least 18 incidents related to battery-wire tracking harnesses that it tracked, including two incidents in which wheelchairs caught fire resulting in the death of their users.

11. Another September 19, 2002 *Cleveland Plain Dealer* report entitled "*Invacare Recall under way on beds, oxygen machines*, told of a 2001 recall of "junction boxes in semi-electric and fully electric beds made from August 1998 to October 2000 and concentrators made by a supplier from November 1994 to January 1997". This bed recall was reportedly due to a part inside the electric bed's "junction box", which controls the motor that adjusts the position of the mattress, and could fail and overheat. This article also stated that "[b]etween 1993 and 2000, Invacare compiled more than 30 complaints related to problems with its chairs' battery charger wiring," among them "two instances where people burned to death" in 1994 and 1995.

12. On August 26, 2003, the FDA sent Invacare another warning letter (the "2003 Warning Letter", a copy which is attached to this complaint as Exhibit 2) following an inspection of the Elyria, Ohio facility in March 2003. According to the 2003 Wanrning Letter, the "inspection revealed that the medical devices [Invacare] manufactures, such as power wheelchairs and power scooters are adulterated within the meaning of Section 501(h) of the [Act], in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the [regulations]." Again, the 2003 Warning Letter indicates violations similar to those described in the earlier Warning Letters and the most

recent 2010 Warning Letter, including adulterated devices, and failure to validate and document processes and quality assurance tests.

13. The existence of rampant and ongoing safety, reporting, and lack of internal control issues at Invacare is also supported by numerous former employees of the Company. These confidential witnesses (hereinafter "CWs") are former employees of Invacare who worked at the Sanford, Florida plant and other facilities. As detailed below, these CW accounts not only corroborate the problems at Invacare, but include observations of affirmative steps to suppress information and opinions concerning incidents of Invacare beds catching fire; in other words, efforts to obfuscate the truth from being disclosed.

14. Thus, these latest safety-related issues at Invacare appear to be just "business as usual" at the Company. Indeed, Invacare also failed to disclose the FDA's recent concerns to shareholders in August 2010, when they first arose, but delayed and waited until the Company received the more serious Warning Letter four months later (the "2010 Warning Letter", a copy which is attached to this complaint as Exhibit 3). When the Company did finally disclose the existence of these issues on January 4, 2011, over two weeks after receipt of the December 15, 2010, FDA letter, it caused Invacare's stock price to drop from $30.67 on January 3, 2011 to $28.60 on January 5, 2011.

15. And, Defendants' public response to the December, 2010 Warning Letter on January 4, 2011 has largely been a spin and damage control approach, with a press release belittling the situation as concerning mere paper-pushing and "documentary procedures" and stating that "[t]he FDA warning letter does not state that [the Company's] products are unsafe nor has it impacted [the Company's] production."

16. Invacare Chief Executive Officer Gerald B. Blouch again sought to minimize the situation by labeling it just "internal documentation and procedural processes"-related issues at the Sanford plant, and chalking it up to increased FDA scrutiny. Blouch rationalized that "[i]n the past year, the FDA has increased its resources and enforcement actions have risen significantly," as if the mere fact of newly increased FDA ability to police violations somehow excuses Invacare's failure to comply with federal law and regulations. Blount's defense is properly translated as: "the FDA is now able to apply greater scrutiny, and is looking harder at us and other violators, so it's no surprise that we got caught", and "even so, it's no big deal."

17. As it has failed to do for years on end, the Company has again failed to address the issues flagged by the FDA, or even take them seriously (as evidenced by, *inter alia*, the 2010 Warning Letter (reproduced in significant part below) that detailed the problems identified in August 2010, and Invacare's inadequate responses to and failure to address those problems).

18. Defendants' reaction to the latest incident is really just more of the same, and the Company's purported "review" of processes is tainted because,as explained on the "Frequently Asked Questions Regarding FDA" page on the Company's website,[2] the "team" tasked with investigating and dealing with the crisis, while purportedly including both internal employees and outside consultants, is not truly independent but is beholden to current management and the Board. This "team" "will report directly to Gerry Blouch, president and [CEO] of Invacare . . ." Blouch, who has been running Invacare for the past fifteen years, is plainly not independent. Blouch has made it clear that he considers the issues raised by the FDA as little more than nuisance and dealing with them as just an exercise in pushing paper.

[2] This was previously posted at http://www.invacare.com/cgi-bin/imhqprd/news/fda-letter-faqs.jsp (but apparently since removed).

19. This lack of independence and Invacare's failure to meet important regulatory and compliance standards appears to have been further reinforced by the astoundingly brief tenure of Invacare's highly-touted new Chief Compliance Officer. In an attempt to create the impression of reform, Invacare created a new CCO position and announced the hiring of Colleen M. Craven, an attorney and past Vice President of Ethics and Corporate Compliance at Endo Pharmaceuticals, Inc. Ms. Craven lasted barely two weeks in the new position before exiting the Company purportedly for "personal reasons." Ms. Craven was quickly replaced with an Invacare insider with an engineering background, but apparently none in regulatory or healthcare compliance.

20. The truth is that the Board has failed to put in place an adequate internal control and compliance system for years, essentially permitting, enabling and encouraging the Company and its management and employees to ignore the FDA's regulations and criticisms and its own internal safety, compliance and record-keeping issues, as shown by, among other things, the 1996 Warning Letter, the 1998 Warning Letter, the 2003 Warning Letter, and the most recent December 2010 Warning Letter. These ongoing and serious failures have worked to the Company's significant detriment. The Defendants' initial failure to properly address the FDA's latest concerns after the FDA's inspection of the Sanford plant, as well as its woefully inadequate response to the 2010 Warning Letter, further confirm that Defendants have failed and continue to fail to fulfill their fiduciary duties. Defendants have failed to take adequate, necessary and appropriate steps to address in any meaningful way, if at all, the serious problems existing for years and highlighted by the FDA. Having failed in this for so long, Defendants' cannot be trusted to do so now.

21. This action seeks to hold the Board responsible for breaching its fiduciary duties of good faith to the Company by ordering, approving, encouraging, and/or acquiescing in policies, processes and practices with respect to safety, regulatory compliance and recordkeeping, including those involving inaccurate reporting and addressing of customer complaints about its products in violation of FDA regulations. The Board, by its fiduciary breaches, has and will continue to foreseeably and materially harm the Company, its business, and reputation.

22. In addition, Plaintiff seeks to ensure that adequate steps are finally taken and measures, controls and safeguards put in place which appropriately reflect the seriousness of the lapses described herein, and finally address the ongoing issues which have been plaguing the Company for years, culminating in the recent actions taken by the FDA.

23. Invacare (as well as its shareholders) have been, and continue to be, harmed from these improper practices because, among other things:

a. The Company has incurred and will continue to incur substantial defense costs associated with on-going governmental and regulatory investigations;

b. The Company will likely face further government and regulatory investigations, complaints and actions, as well as civil lawsuits against it for its practices;

c. The Company has already suffered, and will undoubtedly continue to suffer, significant reputational harm as a result of Defendants' misconduct and the circumstances as outlined herein.

THE PARTIES

24. Plaintiff, City of Lansing Police and Fire Retirement System, is a retirement system with over $250 million in assets under management, created and maintained for the benefit of Lansing's retired police officers and firefighters and their families. Plaintiff is, and has been at times relevant hereto, an owner and holder of Invacare common stock.

25. Nominal defendant Invacare is a corporation organized and existing under the laws of the state of Ohio, with its headquarters located at One Invacare Way, P.O. Box 4028, Elyria, Ohio 44036.

26. Defendant Gerald B. Blouch ("Blouch") has served as President and a director of the Company since 1996. On January 1, 2011 Blouch became the CEO of Invacare after serving as interim CEO since April 2010. Previously, Blouch has also served as Chief Operating Officer, Chairman–Invacare International (a wholly-owned Invacare subsidiary) and the Chief Financial Officer and Treasurer of Invacare.

27. Defendant Aaron Malachi Mixon III ("Mixon") has served as a director of the Company since 1979 and Chairman of the Board since 1983. Mixon has also previously served as the Company's CEO and President. Mixon was also a founder of Invacare, and just recently retired as the Company's CEO in 2010.

28. Defendant Joseph B. Richey II ("Richey") has served as a director of Invacare since 1980 and has been President-Invacare Technologies and Senior Vice President-Electronic and Design Engineering. Richey was a founder of Invacare and has been a driving force behind the Company's product development.

29. Defendant Michael F. Delaney ("Delaney") is a director of the Company and has served as such since 1986.

30. Defendant Dan T. Moore III ("Moore") is a director of Invacare and has served as such since 1980. Moore was a founding investor of Invacare.

31. Defendant William M. Weber ("Weber") is a director of the Company and has served as such since 1988. Weber was a founding investor of Invacare and serves as Chair of the Audit Committee of the Board.

32. Defendant James L. Jones ("Jones") is a director of the Company and has served as such since 2010.

33. Defendant C. Martin Harris ("Harris") has served as a director of the Company since 2003.

34. Defendant Dale C. Laporte ("Laporte") is a director of the Company and has served as such since 2009. Previously, Laporte served as Senior Vice President-Business Development and General Counsel of the Company.

35. Defendant Charles S. Robb ("Robb") has served as a director of the Company since 2010.

36. The defendants identified in ¶¶ 26-35 constituted the Invacare Board, at relevant times alleged herein, and may be collectively referred to herein as the "Individual Defendants."

JURISDICTION AND VENUE

37. Jurisdiction lies with this Court pursuant to OHIO REV. CODE ANN. § 2305.01.

38. The Individual Defendants are all members of the Board of Invacare, a company organized under the General Corporation Law of the State of Ohio.

39. Each defendant is subject to the jurisdiction of the Ohio courts by virtue of their doing or transacting business in Ohio.

40. Venue is proper in this Court pursuant to OHIO R. CIV. P. 3. Invacare is organized and domiciled in the State of Ohio. The Individual Defendants are all members of the Board of Invacare. The actions of the Defendants that give rise to Plaintiff's claims for relief took place in Lorain County, Ohio.

SUBSTANTIVE ALLEGATIONS

41. Invacare Corporation is reportedly the world's leading manufacturer and distributor of medical equipment and supplies used in the home, based on its distribution channels, breadth of product line and net sales. The Company reportedly sells its products principally to over 25,000 home health care and medical equipment providers, distributors and government locations in the United States, Australia, Canada, Europe, New Zealand and Asia, and also distributes medical equipment and disposable medical supplies manufactured by others.

The FDA's December 15, 2010 Warning Letter to Invacare Is The Latest in a Series of FDA Warning Letters Detailing Serious Violations of FDA Regulations

42. FDA Warning Letters are not trifling matters; rather, they are indicative of serious problems, and that a company has committed significant legal or regulatory violations. According to the FDA's Regulatory Procedures Manual (March, 2010), a Warning Letter is "a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations" and is "one of the Agency's principal means of achieving prompt voluntary compliance with the [Federal Food, Drug and Cosmetic] Act [the "Act"]." A Warning Letter "notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the [Act], its implementing regulations and other federal statutes." Warning Letters are only to be issued "for

violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected."[3]

43. As a result of an August, 2010 inspection of the Company's Sanford, Florida facility (one of the Company's four major manufacturing facilities), the FDA issued a Warning Letter to Invacare on December 15, 2010. This Warning Letter outlined a host of serious deficiencies, and stated, in part:

> During an inspection of your firm located in Sanford, Florida on August 2, 2010 through August 18, 2010, investigators from the [FDA] determined that your firm manufactures manual, electric, and semi-electric beds. Under section 201(h) of the [Act], 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.
>
> ***This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820.*** We received a response from Ronald J. Clines, Director Regulatory Affairs and Corporate Quality Systems dated September 8, 2010, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:
>
> ***1. Failure to establish and maintain adequate procedures to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems and to employ appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 CFR 820.100(a)(1). For example, your firm failed to analyze MDRs, adverse events, or product complaints during trend analysis by problem codes including those for entrapment and potential fire hazard.***

[3] This is in contrast with an "Untitled Letter," which is defined by the FDA as "an **initial** correspondence with regulated industry that cites violations that do not meet the threshold of a Warning Letter." (Emphasis in original).

Your firm's response dated September 8, 2010, is not adequate. Your firm has stated that you are investigating ways of improving trending of more serious allegations such as entrapment and fire risk. Your firm further stated that complaints of this type are trended during Product Safety Committee meetings which are held on a quarterly basis at a minimum. According to your firm's CAPA procedure, BB14-001, Quality Assurance analyzes these complaints and quality data to detect trends in failures requiring corrective action. Your firm's procedure does not however clearly identify the requirements for analyzing complaints or discuss what statistical methodology will be utilized to detect recurring problems which is a requirement under 21 CFR 820.100(a)(1). In addition, your firm has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

2. ***Failure to establish and maintain adequate procedures to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3).*** For example, Section 5.1.1.1 of your firm's Corrective and Prevention Action procedure, BBI4-001, states, "Nonconformances that are repeating problems (trends) ...require documented evidence of corrective action." Additionally, Sec's 5.3, 5.4 and 5.5 of your firm's Customer Complaints procedure, BB14-002, states, "Quality Assurance designee ... reviews the investigation as well as corrective/preventive action documented to determine the appropriateness of the same. Upon completion of the failure investigation and determination of the corrective/preventive action, the results will be reviewed with the Quality Manager. Completed Inspection Report Forms are reviewed and approved by Quality Assurance Manager..."

However, recurring complaints relating to potential sparks/fires associated with the beds did not contain a documented determination of the action(s) needed to correct and prevent recurrence of the nonconformances, such as:

a) Complaint # 5426 dated July 26, 2010, references a user who alleges the device was sparking when the pendant was plugged in.

b) Complaint # 5208 received June 25, 2010, references a driver set-up an Invacare bariatric bed and found no power to the bed. A burning smell was noted but no actual smoke.

c) Complaint # 4894 received June 2, 2010, references the junction (control) box of an Invacare bariatric bed caught fire and two patients were taken to the hospital and treated for smoke inhalation and chest pain. Visible flames were observed, however when the unit was unplugged the fire went out.

d) Complaint # 4521 received April 13, 2010, references a fire started at the foot of an Invacare bed (model # unknown) resulting in a consumer's death.

Additionally, the following complaints relating to entrapment with the use of your firm's bed rails did not contain a documented determination of the action(s) needed to correct and prevent recurrence of the nonconformances, such as:

a) Complaint # 4234 dated February 17, 2010, references that there was an alleged death of patient and entrapment with Invacare bed between the bottom of the rail and the top of the mattress. It is documented in your firm's investigation that health care facility personnel stated a coroner's report indicated that the patient suffered a heart attack and then was allegedly entrapped post mortem.

b) Complaint # 4181 received February 11, 2010, references a consumer that alleges an Invacare bed system allowed his wife's head to get stuck between the rail and mattress causing her suffocation.

Your firm's response dated September 8, 2010, is not adequate. Although your firm stated you have taken actions to increase awareness to your customers and users regarding entrapment, you also stated they were incremental in nature and were not to correct any identified product defect of malfunction. Your firm also stated moving forward, you will continue to examine entrapment risks and is considering adding additional instruction regarding body size as it may relate to increased entrapment. However your firm's response did not discuss or provide any evidence of their process for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems. In addition, your firm has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

3. Failure to maintain an adequate record of the investigation including the dates and results of the investigation, as required by 21 CFR 820.198(e). For example, complaints received by your firm did not include an adequate written record of the dates and results of the investigation, such as:

a) Complaint # 4894 received June 2, 2010, references that the junction (control) box of an Invacare bariatric bed caught fire and two patients were taken to the hospital and treated for smoke inhalation and chest pain.

b) Complaint #4522 received April 13, 2010, references an Invacare bed and bed rail that was allegedly involved in a bed entrapment death of a child (age 11).

Your firm's response dated September 8, 2010, is not adequate. Your firm has stated you reviewed your current complaint investigation process and although not specified, are exploring solutions that would document and define "Critical Information" requirements and the attempts to gather this information. Your firm has stated that these corrective actions would be completed by October 15, 2010; however, you have not provided any evidence of implementation of changes to the current investigation process. Your firm also stated you documented a risk assessment specifically to the potential fire issue and will submit it to FDA by

October 15, 2010. Your firm also provided updates on several of the complaints mentioned in this observation, which included additional information you received from your investigation or the status of pending information. You further stated you would like improvement on how investigations are documented especially with regard to information that Invacare requests but is not provided or denied. Although you state that many complaints involve product that has been in rental fleet for years, the history is unknown, or the provider has no information regarding the product use, you did not mention how you will ensure that the dates and results of complaint investigations are adequate. Additionally, your firm did not discuss how you will conduct a systemic corrective action that involves re-assessing all complaints to ensure that the investigations were adequately completed and documented.

4. ***Failure to establish and maintain adequate procedures for validating the device design in order to ensure that devices conform to defined user needs and intended uses, and perform risk analysis where appropriate, as required by 21 CFR 820.30(g).*** For example, Section 7.8 and 7.9 of your firm's procedure, CP04-013, for Risk and Hazard Assessment Process states, "If information is obtained from production or post-production activities that suggests the existing risk assessment may not reflect current information, this information is assessed to determine if a need exists to modify the existing risk assessment. The Risk and Hazard Peer Review will address ...Have risk[s] been estimated for each identified hazard? Are the risk[s] acceptable? (i.e ... will misuse increase the likelihood of failure, etc.?" Additionally, Sec 8.1.1 states that in using the risk assessment form, the following device characteristics at a minimum are to be considered for each corresponding section, "device or component failure (special intervention) ... user operation requirement (instructions for use/maintenance) ... device interaction with other devices/substance."

However your firm has failed to update the risk analysis for the Invacare bed systems with the following post-production information:

a) Risk of entrapment associated with the firm's bed systems including but not limited to non-Invacare mattresses/bed rails or use with smaller size patients except for CS (Carroll Series) Long Term Care Bed Systems, whose formal risk analysis does include patient entrapment issue but also does not include use of devices by smaller size patients.

b) Risk assessment concerning Echo, Arro, and CS Invacare Beds with all Invacare mattresses including but not limited to models # 5180, 5184 and 5185.

c) Risk of improper installation of bed rails for the bed systems except for CS (Carroll Series) Long Term Care Bed Systems.

d) Risk Assessment for warning label that was used on Invacare model # 5185 mattresses in order to reduce risk of entrapment on August 1, 2007, however the investigator was informed that the firm stopped using this label on model #

5185 mattresses on February 21, 2008. The firm stated they believed it was redundant since the same information was being included in instructions for use for full length bed rails (released on December 6, 2007). In addition, the firm did not document when the new instructions for use were initially distributed with the product.

Your firm's response dated September 8, 2010, is not adequate. Your firm has stated that you will conduct a risk assessment regarding bed rail entrapment with the intent of determining if the areas of concern that are not currently addressed, such as patient size, or if existing labeling can be augmented in some way. Your firm also stated that these activities will be completed by October 30, 2010; however, you have not provided any evidence of implementation of this corrective action. Your firm further stated that risk assessment is conducted as part of the product development process and as part of the complaint handling process when malfunctions are identified. In addition, you stated that you have been proactive in addressing bed rail entrapment risk before the FDA guidance document in March 2006. However your firm's response did not address other issues associated with the mattresses or bed rails or how, according to your procedure, CP04-013, information obtained from production or post-production activities that suggests the existing risk assessment may not reflect current information will be assessed to determine if a need exists to modify the existing risk assessment. Additionally, your firm did not discuss how you will conduct a systemic corrective action that includes a retrospective review and reevaluation of other types of complaints to ensure that the risk analysis has been appropriately updated.

5. ***Failure to establish adequate procedures for identifying training needs for ensuring that all personnel are trained to adequately perform their assigned responsibilities and for documenting training, as required by 21 CFR 820.25(b).*** For example, Sec 3.2.6 of your firm's Complaint Handing and Medical Device/Vigilance Reporting Procedure, CP14-002 states Customer Affairs, "Provides training to new customer service representatives regarding Adverse Event complaints and current methods for reporting quality problems and incidents. Training may also be provided to the sales force or other key contact employees when appropriate". Section 3.32 further states Regulatory Affairs "Reviews previous complaint history, FDA Maude database, or previous FDA MDR database to review previous related incidents for similarities or trends... Updates the complaint database system with analysis data, inspection status and material location as required."

a) ***However, a review of the training of customer service personnel showed no documentation that the following customer service personnel have ever received training on the firm's complaint handling procedures although they received at least the following complaints:***

(b)(6) (File # 2837 dated June 24, 2009), **(b)(6)**(File # 3490 dated September 21, 2009), **(b)(6)** (File # 4152 dated February 1, 2010) and **(b)(6)** (File # 4181 dated February 11, 2010).

b) The following Invacare customer service personnel also took part in complaint handling activities prior to obtaining documented training on complaint handling:

(b)(6) (# 2045 dated February 9, 2009), **(b)(6)** (File # 2267 dated February 23, 2009), **(b)(6)** (File # 2848 dated June 4, 2009), **(b)(6)** (File # 3839 dated November 23, 2009) and **(b)(6)** (File # 4023 dated January 5, 2010).

c) Additionally, during the inspection, the investigator observed that Regulatory Affairs failed to review previous complaint history or FDA Maude (MDR) database to review previous related incidents for similarities or trends and update the complaint database system with analysis data as required.

The adequacy of your firm's response dated September 8, 2010, cannot be determined at this time. Your firm stated you were reviewing the training of the current Customer Service Staff and were providing additional training as needed. Additionally, the on-boarding process for new customer service staff was reviewed to ensure that new associates in the future have documented training in place prior to processing calls of this type. These activities were expected to be completed by October 15, 2010; however, your firm has not provided any evidence of implementation of these corrective actions.

Our inspection also revealed that your Invacare medical beds devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 C.F.R. Part 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

Failure to report to the FDA no later than 30 calendar days after the day that you become aware of information, from any source, that reasonably suggests that a device that you market has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example: Two complaints that should have been reported to FDA as malfunction MDRs are Complaint #2850, dated June 3, 2009,* "Consumer alleged her control box on the bed caught fire", *involving the Bariatric Bed, Model #BAR600IVC; and Complaint #4470, dated March 29, 2010,* "Head motor sparked and smoked during bed set up, then stopped working" *involving the Bariatric Bed, Model #BARPKGIVC-1633.

Your firm's response dated September 8, 2010, did not address this charge because it was not on the FDA 483 issued to you at the end of the inspection.

> ***You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the [FDA] without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.***
>
> * * *
>
> ***Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility.*** It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violations and to bring your products into compliance.

(Emphasis added).

Defendants' and the Company's Misleading and Misguided Attempts to Deflect and Minimize the Significance of the FDA's Warning Letter

44. Despite the FDA 2010 Warning Letter's serious implications, Defendants and the Company took an extremely defensive approach to the 2010 Warning Letter, misleadingly seeking to downplay its implications. Blouch's January 5, 2011 comments, which were previously posted on the Company's website, sought in large part to explain away the recent Warning Letter as simply a byproduct of recent enhanced enforcement efforts, stating that "***[i]n the past year, the FDA has increased its resources and enforcement actions have risen significantly***. . . ." (emphasis added). Blouch also represented, *inter alia*, that:

> It is also important to know that the FDA letter specifically focuses on internal documentation and procedural processes at the Sanford facility. It does not call into question the safety or efficacy of Invacare products, and it has not impacted

> production. Of the complaints that are detailed in the letter, investigations to date show that no injuries or deaths were caused by a product defect.

45. Thus, despite other representations, the Defendants' essentially reacted to this crisis by seeking to minimize its significance of the situation, ascribing it to merely increased regulatory scrutiny and minor recordkeeping problems. A review of the 2010 Warning Letter reveals this to be misleading and a further indication that Defendants have not acted appropriately to the issues raised by the FDA, either now or in years past.

46. For instance, as referenced above, the FDA found that Invacare's beds at issue should be considered "adulterated" within the meaning of 21 U.S.C. § 351(h), Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are inconsistent with the Current Good Manufacturing Practice requirements of the Quality System regulation found at 21 C.F.R. § 820, and that the Company lacked internal controls to reliably report and address malfunctions with its automatic beds, including incidents in which the beds allegedly caught on fire causing injury and death. Despite Invacare's misleading efforts to downplay them, these are serious issues and are reflective of a culture of disregard for basic oversight and safety concerns.

47. The Company continued its efforts to mischaracterize the situation, including adding a page on its website titled "Frequently Asked Questions Regarding the FDA Letter," which stated, in part:

> Why did Invacare receive a warning letter from the FDA?
>
> ***After an inspection of Invacare's Sanford, Florida facility, Invacare received a warning letter from the FDA related to internal process issues and documentation procedures.*** The letter did not call into question the safety or efficacy of Invacare products, and it has not impacted production. Invacare is taking the FDA's concerns very seriously and will address them appropriately.
>
> Will the FDA warning impact Invacare's operations?

> To ensure that Invacare will continue to meet or exceed all regulatory requirements, the Company has assembled a team of internal quality and regulatory associates and outside experts to review the FDA's comments and recommend enhancements or improvements. ***This team will report directly to Gerry Blouch, president and CEO of Invacare and will ensure that the solutions we initiate are meaningful and permanent. In fact, as the team looks at possible enhancements or improvements at Sanford, these changes will be considered for all Invacare facilities.***
>
> It appears that Invacare has several complaints about its products. How do you know they are safe?
>
> Invacare's products are used by millions of consumers worldwide, and we are proud of our more than 30-year legacy of helping patients live life better. Like any company with millions of products in service, Invacare sometimes receives questions or concerns from customers. All customer comments are taken very seriously.
>
> Invacare respects the FDA's role in ensuring that all medical products companies achieve the agency's standards, and we look forward to addressing the FDA's concerns and making any enhancements or improvements necessary to ensure that we will meet or exceed all regulatory requirements.
>
> What can I do to verify the safety of my Invacare product?
>
> ***The FDA letter specifically focuses on internal documentation and procedural processes at the Sanford facility. Invacare has no reason to believe the questions raised in the letter change the safety profile of Invacare products when used as directed.*** The best measure a customer or patient can take to ensure the safety of their products is to follow the safety and maintenance instructions provided in their Owners and Operators Manuals.

48. Defendants have given lip service to taking the FDA's concerns "seriously" (e.g., claiming that safety was the "highest priority," that it "respected the FDA's role in ensuring that all medical product companies achieve compliance with the agency's standards and regulations," etc.), but the overarching theme of the Company's response was to minimize the situation and attempt to spin it as just a minor problem of paper having been pushed in the wrong direction. The Company's February 25, 2011 Annual Report also made similar statements about the FDA's investigation and the 2010 Warning Letter.

49. The Defendants' latest promise in response to the 2010 Warning letter to address the FDA's concerns "quickly and completely" is also unconvincing, considering, among other things, that these and similar issues have been ongoing at Invacare for years, without having been adequately addressed, much less eliminated.

50. The Company's response that it was "assembl[ing] a team of internal quality and regulatory associates and outside experts to review the FDA's comments and recommend enhancements or improvements at our Sanford plant" must be viewed with extreme skepticism as well, considering again that these issues have apparently been allowed to persist and have been pervasive at Invacare for years. The fact that this "task force" will be headed by and report directly to none other than Defendant Blouch, who has presided over the Company for almost fifteen (15) years, further confirms that it will thus lack any true independence or authority. Thus, the Defendants' boilerplate promises to "ensure that the solutions we initiate are meaningful and permanent" ring rather hollow and meaningless.

51. On January 4, 2011, the Company also announced that it had submitted comments in regard to the 2010 Warning Letter. This press release also referenced the creation of this new "team" headed by Blouch, and stated, in part:

> Today Invacare Corporation commented on an FDA warning letter related to an inspection of the Company's bed manufacturing facility in Sanford, Florida. The warning letter takes issue with Invacare's compliance with the FDA's Quality System Regulation, specifically related to Invacare's ability to establish and maintain adequate procedures to analyze processes and operations and to document actions taken on product complaints.
>
> "Invacare wants to assure users and the general public that we rigorously test our products and stand fully behind the safety of our products. The FDA warning letter does not state that our products are unsafe nor has it impacted our production. ***The letter is related to documentation procedures.*** We take all FDA matters very seriously, and we intend to address all of the FDA's concerns," said Gerald B. Blouch, president and [CEO].

(Emphasis added).

52. This new "team" gained and then lost its new Chief Compliance Officer in the space of a few weeks, under circumstances appearing to cast even more doubt on its already severely limited credibility and the true state of Invacare's internal controls and compliance safeguards.

53. On April 4, 2011, the Company issued a press release titled "Invacare Corporation Continues To Enhance Its Internal Regulatory & Corporate Compliance Functions With New Role Of Chief Compliance Officer," announcing that it had hired Colleen M. Craven, an attorney and formerly the Vice President of Ethics and Corporate Compliance at Endo Pharmaceuticals, Inc. (and a past regulatory/compliance consultant at PriceWaterhouseCoopers), to be the CCO.

54. Invacare's April 4 press release touted Craven's arrival:

> In this role, Craven will be responsible for overseeing the Company's initiatives to ensure it is in compliance with relevant laws and regulations regarding the design, manufacture and distribution of medical devices. Craven joins Invacare as the Company looks to improve its corporate compliance procedures and documentation practices.
>
> "As Invacare Corporation has grown into a $1.7 billion medical device manufacturer, it has realized that there is a lot of opportunity to make improvements to its corporate procedures and documentation practices. We look forward to Colleen's contributions to the team. The Company will continue to look for opportunities to add talent and expertise to expand its regulatory affairs capabilities," said Gerald B. Blouch, . . .

55. However, just after she was hired Craven did an abrupt about face and decided not to make any such "contributions to the team," resigning barely two weeks later on April 22. Invacare cited the stock refrain of "personal reasons" for her rapid departure. The circumstances and timing of Craven's resignation obviously appear to raise further questions about the true state of Invacare's internal controls and compliance safeguards.

56. After Craven's departure, rather than conduct a search for another outside person with compliance experience to fill the new position, the Company went in-house, naming Doug

Newlin, Senior Vice President of Global Engineering (someone with an engineering pedigree but no apparent significant compliance background) as the new CCO.

These Internal Controls, Compliance and Safety Issues Have Been Persistent and Pervasive at Invacare for Well Over a Decade, During Which the Board and Management have Failed to Resolve or Even Adequately Address Them

57. The issues relating to the Company's beds and other products, FDA violations, and the critical record keeping and complaint handling procedure and practice failures, date back over a decade, at a minimum. The persistence of these or similar problems for so many years indicates an ongoing and alarmingly familiar pattern and course of conduct which stretches at least as far back as the mid-1990s, if not farther.

58. For example in 1996, as it is now, the FDA was issuing serious warnings to the Company concerning its failure to comply with Good Manufacturing Practices (GMP) and Medical Device Reporting (MDR) principles. An August, 1997 article appearing in *HighBeam Research* (and contained on the website Highbeamresearch.com) entitled *Invacare, FDA Dispute Intent of GMPs, MDRs (Good Manufacturing Practices, Medical Device Reporting*) reported that the FDA had followed a January, 1996 inspection with a nine-page Warning Letter in May, 1996 (concerning the Sanford facility), revealing that "a variety of record-keeping problems haunt Invacare in its dealings with the FDA and that the agency was unswayed by the firm's attempts to defend its practices with its own interpretations of [GMP] and [MDR]." According to the article, this earlier FDA investigation "hit [Invacare's] complaint-handling procedures particularly hard, but also slapped change controls, process and testing validation and component acceptance, according to the recently released 483."[4]

[4] This refers to Form 483 Inspectional Observations.

59. The serious issues at the Company did not end with the 1996 Warning Letter. Barely two years later, Invacare received another Warning Letter, the 1998 Warning Letter, after an inspection by an FDA investigator on July 22, 1998 of the Sanford, Florida facility. The 1998 Warning Letter outlined a host of serious deficiencies quite similar to those in both the 1996 Warning Letter and the multiple warning letters to follow, including the 2010 Warning Letter. The 1998 Letter stated, in part:

> We are writing to you because on July 22, 1998, FDA Investigator Ronald T. Weber collected information that revealed ***serious regulatory problems involving electric patient beds***, lift out chairs, and adjustable, automatic air mattresses, which are manufactured and distributed by your firm in Sanford, Florida.
>
> * * *
>
> ***The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Quality System (QS) regulation [Title 21, Code of Federal Regulations (C.F.R.), Part 820]. These violations include, but are not limited to, the following:***
>
> 1. Failure to validate and document significant manufacturing processes and quality assurance tests to assure specific requirements are met, e.g., robot and manual welding processes, and software used to program the chip in the control device of the automatic air mattress.
>
> Your firm's response dated July 30, 1998...to Item #1 is inadequate because no documentation of the software validation was provided or available to the investigator for his review, nor is it provided in the response....
>
> 2. Failure to establish and maintain device history records (DHR's) demonstrating devices are manufactured and tested in accordance with the DHR and other requirements of the QS regulation, e.g., there are no DHR's for the manufacture of the eletric beds and left out chairs.
>
> * * *
>
> Your firm's response dated July 30, 1998 to Item 2 is inadequate because your Quality Manager (QM) stated during the inspection that there are no records of finished product inspection or release for distribution. He said the only record kept was of the serial numbers used, which identify the production number and date of manufacture.

3. Failure to establish and maintain procedures for implementing corrective and preventive actions, e.g., there are no procedures and/or documentation ensuring that the actions taken are effective and do not adversely affect the finished device; and that information is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

Your firm's response dated July 30, 1998 to Item 3 is inadequate because your QM stated that audits of returns and complaints were conducted a month later to determine if evidence of the failure mode still existed. As was explained during the inspection, all corrective actions require verification or validation prior to release of the device to distribution. Further, your QM state that no verification or validation of a correction action is conducted, and there is no documentation covering these activities.

* * *

4. Failure to establish procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned responsibilities and that all training is documented, e.g., your QM stated that he had no formal training in GMP's, the QS regulation, process validation, design control and other areas that a person in this position would be required to manage. Your QM stated that he had a one day course in ISO 9000 which was documented, and was scheduled to attend a 2 day course on process validation.

Your firm's response dated July 30, 1998 to Item 4 is inadequate because the response fails to address the QM's lack of specific training for the responsibilities for which he has authority. The QM is obviously qualified for the position he holds and no one is disputing that, however, he obviously has received little training dealing specifically with the areas that he is directly responsible for supervising including: process validation, design control as it relates to manufacturing, finished device testing, corrective and preventive actions, failure investigations, complaint handling etc. Without documentation of these activities, there is no way for FDA to determine a person's ability to adequately manage and supervise. You response states that all employee training will be conducted and documented. This observation will be verified during the next inspection of your firm.

Failure to include and implement written procedures to define and identify returns as complaints, to review and evaluate all complaints including returns to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803 or 804, and to assure failure investigations and corrective and preventive actions are conducted and documented, e.g., according to documentation collected by the investigator, your firm collects some data conducts trend analysis of product returns, however, the QM stated that investigations are not

conducted and documented pursuant to a procedure to make the determinations noted above.[5]

* * *

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

* * *

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

* * *

(Emphasis added).

60. A September 1, 2002 news article in the *Cleveland Plain Dealer* entitled "*Fires, deaths linked to Invacare wheelchairs*" recounted wiring and battery-charging defects which caused fatal fires in Invacare's wheelchair products, and a recall covering hundreds of thousands of Invacare wheelchairs manufactured between 1985 and 2000. According to that article, and Invacare's complaint files, the Company violated FDA regulations by failing to report at least 18 incidents related to battery-wire tracking harnesses that it tracked, including two incidents in which wheelchairs caught fire resulting the death of their users. This only further highlights the

[5] While at the time the FDA deemed Invacare's to this item "appear[ing] to be adequate," subject to verification, but any such remedy seems to have been short-lived and ineffective considering that Invacare was subsequently repeatedly cited for its failure to adequately report and track complaints, as well as other serious documentation and reporting failures.

pervasive culture of noncompliance with FDA regulations that has persisted at Invacare for many years.

61. Another *Cleveland Plain Dealer* article appearing on September 19, 2002, entitled "*Invacare Recall under way on beds, oxygen machines*, reported a 2001 recall of "junction boxes in semi-electric and fully electric beds made from August 1998 to October 2000 and concentrators made by a supplier from November 1994 to January 1997" due to a part inside the electric bed's junction box, which controls the motor that adjusts the position of the mattress, and could fail and overheat. Invacare's former Director of Regulatory Affairs testified during litigation that this junction box/motor issue in Invacare's beds presented a risk of fire, and the news report stated that both the Company and the FDA had received complaints about the failure of this motor component. This article also reported that "[b]etween 1993 and 2000, Invacare compiled more than 30 complaints related to problems with its chairs' battery charger wiring," among them "two instances where people burned to death" in 1994 and 1995.

62. In August 2002, the Company reportedly settled a lawsuit for $7 million after defective wiring on one of its wheelchairs sparked and caught fire, badly burning an elderly quadriplegic woman. Around the same time, the Company was also facing three other lawsuits involving deaths caused by the same line of wheelchairs. The Company did not begin recalling these wheelchairs until years after reports surfaced that they were igniting and causing deaths and injuries.

63. The following year, Invacare received yet another Warning Letter, after an unsatisfactory inspection by an FDA investigator of the Elyria, Ohio facility, which took place between March 10 and 25, 2003. Again, the 2003 Warning Letter outlined a host of serious

deficiencies by all appearances quite similar to those in the 1996, 1998 and 2010 Warning Letters. The 2003 Warning Letter stated, in part:

> Investigators from the Food and Drug Administration (FDA) inspected your firm's facilities located at 1200 Taylor Street, 899 Cleveland Street, and One Invacare Way in Elyria, Ohio, between March 10 and 25, 2003. This inspection revealed that the medical devices your firm manufactures, such as power wheelchairs and power scooters are adulterated within the meaning of Section 501 (h) of the [Act], 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820 (QSR) as follows:
>
> 1. Failure to establish and maintain adequate procedures for the identification, documentation, validation or where approriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).
>
> For example, the [redacted] fuseholders used with [redacted] wire in the battery box assemblies were used in an application that was outside of the manufacturer's recommended specifications for these components without adequate validation or verification of this design change based on the application in which these components were used....
>
> In addition, testing that was performed on the wire/fuse/fuseholder assembly was not completed until after these components were used in production.
>
> Your firm did not adequately validate the ability of the [redacted] wire to handle operation above its rating. Engineering tests were conducted to verify that the wire insulation was not damaged when subjected to temperature stresses in a lab setting. . However, the ability of the [redacted] wire to handle the increased current was not validated for its intended use because the testing your firm performed does not reflect the actual conditions in which this assembly is used (e.g., connected to a battery inside the battery box installed in a wheelchair).
>
> 2. Failure to have a complaint procedure that ensures that all complaints involving the possible failure of a device to meet any of its specifications are adequately reviewed, evaluated, and investigated, as required by 21 C.F.R. 820.198(c).
>
> ***The FDA Investigator reviewed all of the complaints pertaining to alleged fire-related incidents that Invacare received from October 1, 2002 to March 10, 2003. The majority of these 41 complaints involved smoking caused by a faulty gearbox seal. There was no documentation to show that Invacare investigated and evaluated these complaints to determine whether the smoking gearboxes are a safety concern.***

3. Failure to establish and maintain adequate procedures for in-process acceptance activities including inspections, tests, or other verification activities to ensure that specified requirements for in-process product are met, as required by 21 CFR 820.80(c).

* * *

The actions Invacare has taken appear adequate to correct some, but not all, of the deficiencies FDA observed during these inspections. We consider Invacare's responses to be inadequate in the areas identified below.

With regard to item 1 above (FDA 483 observation #3), Invacare responded in a letter dated March 31, 2003, that "The actual problem identified here was that such testing and qualification, though done before implementation of the fuse holder back in 2000, was not documented." As Invacare's March 31st letter acknowledges, documented testing was not performed until several months after the fuseholder had been put into use. In responses dated May 15, 2003 and May 20, 2003, Invacare stated that the manufacturer's recommendations are based upon a continuous load condition and users are instructed to check the requirements based on the specific applications. According to Invacare's responses, tests were performed to verify that the wire gauge size and fuseholder range are adequate for Invacare's specific application. ***Invacare acknowledged, however, that there were four reports regarding heat deformity and melting of the [redacted] fuseholders.*** The damaged samples were examined by an outside consultant, [redacted] Invacare stated that the report by [redacted] verifies the use of the [redacted] fuseholder for your application, and that Invacare subsequently decided to switch to a new fuseholder (via ECN #0303057) for use in production in April 2003. The reason stated for this switch was for reliability reasons.

The responses to this issue are inadequate because Invacare has not provided sufficient information regarding the corrective and preventive actions taken to address the root cause and failure mode of the reported heat deformity and melting of the [redacted] fuseholders. Although the report by [redacted] does not consider the incidents of heat deformity and melting of these fuseholders to be a fire hazard, the report does present a potential cause for these incidents. According to the report, vibration may cause weakening of the electrical connection between the fuseholder receptor and the stranded [redacted] wire, which in turn will cause heating under load and certain ambient conditions. It does not appear that Invacare has conducted additional testing to confirm this potential failure mode and to determine the actual root cause and failure mode. Invacare also has not provided adequate information regarding the corrective and preventive actions taken to address powered wheelchairs that have the [redacted] fuseholders used with the [redacted] wire that are still in commercial distribution. In reference to the heat deformity and melting of the [redacted] your firm states in its letter dated May 15, 2003, that "though there was no perceived safety hazard, Invacare chose to change to a different fuseholder." However, our review of the

information and data provided for the damaged [redacted] fuseholders indicates there may be a potential safety hazard.

* * *

With regard to item 2 above (FDA 483 observation #2), Invacare's response letter dated March 31, 2003 discussed the steps being taken to correct the deficiency noted regarding the evaluation of complaints involving the possible failure of a device to meet specifications. ***Whereas Invacare stated that a new procedure would be implemented in April 2003 to describe the process to be followed for such assessments, there was no indication that Invacare plans to perform a safety assessment for the complaints identified by the FDA Investigator regarding power wheelchairs that were smoking due to a gearbox seal leak.***

With regard to item 3 above (FDA 483 observation #4), Invacare's March 31, 2003 letter indicated that your firm plans to review all in-process testing or checks to see which ones are effective in identifying problems early in the assembly process and that you will ensure that those identified as worth keeping are properly described in a procedure and documented. The letter further stated that this review may take until year-end to complete. ***However, there was no indication that Invacare would make an assessment of any corrective actions needed for the products that were produced without testing according to a written procedure and for which there was no documentation that the in-process testing was performed.***

Invacare should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies will be advised of the issuance of this warning letter so that they may take this information into account when awarding government contracts.

* * *

(Emphasis added).

Statements By Former Invacare Employees Indicate Ongoing Compliance and Safety Issues at Invacare, Including at the Sanford, Florida Facility

64. Despite FDA's repeated determinations of problems and internal control shortcomings at Invacare, the violations have nevertheless persisted. Interviews with multiple knowledgeable former Invacare employees further confirmed this. These CWs indicated the existence of rampant and ongoing safety, reporting, and lack of internal control issues at Invacare. These CWs, long-time former employees of Invacare at the Sanford, Florida facility

and elsewhere, reported not only serious problems but affirmative steps to suppress information and opinions concerning incidents of Invacare beds catching fire and obfuscate the truth from being disclosed.

65. For instance, CW1, a former Returns Inspector/Quality Auditor worked at the Sanford facility for over a decade. CW1 recounted instances in which she[6] was ordered by her superiors at Invacare to avoid giving honest assessments of the circumstances and causes of incidents involving Invacare bed fires and instead just offer "standard phraseology," boilerplate disclaimers that the products had been adequately tested beforehand and nothing had been found.

66. CW1 was employed by Invacare for over 20 years and was a Returns Inspector/Quality Auditor for a significant part of her employment with the Company at the Company's Sanford, Florida facility. CW1 informed of the many instances where she observed and evaluated beds that were returned, and told of the Company ignoring her professional opinions. CW1 indicated that the Company ultimately "felt like they had to get rid of me."

67. CW1 recalled that as a Returns Inspector she observed several conditions that could cause a risk of fire with Invacare's beds, including external and user-created conditions, and stated that "***[n]ow, that was just honest inspection work, but I was not always allowed to state my findings because the Quality Manager at that time had a totally different view of what my role was -- it was, you know -- cover up!***"

68. CW1 recalled that at some point Invacare discovered that the Control Boxes used in the bed motors were susceptible to being penetrated by liquids, and in order to alleviate this problem, Invacare proceeded to design encasements for the Control Boxes using a process called "potting." CW1 stated that: "We went to a potting material at that time, which of course caused

[6] All CWs are referred to herein as female, regardless of gender.

everything to heat-up! No heat dissipation whatsoever. But, still the snub-circuit should have allowed [the control box] to cut out at a certain temperature. It was hard to figure out what would happen or what would actually go on inside a control box with potting materials." CW1 recalled that during her time at Invacare, the Sanford facility was substantially stripped of engineering personnel, so that the Company's bed products could be made elsewhere.

69. CW1 also stated that during her tenure at Invacare, she would be directed to answer FDA letters such as the 2010 Warning Letter. CW1 was instructed how to respond to such letters by the Company -- she was to indicate that the Company's facility had no information regarding the medical devices once they leave the facility, and that the products were all adequately tested. CW1 stated that she would be put in a position where she would have to respond "with standard phraseology . . . blah blah blah. We're not certain what happened to it after it left our facility but it was tested 100% before it left -- it's cycle-tested up to this and that -- you know meaningless."

70. CW1 specifically recalled an instance where a returned Invacare bed that had caused the death of a customer. Upon close inspection of the burnt bed, it was apparent to CW1 that the fire started beneath the bed. Again, CW1 was instructed to report that adequate testing was performed and that the findings were inconclusive. CW1 added that she "was not allowed to tell the truth" but instead directed to say "[n]o, we tested it this way and that way . . . and we didn't find anything!" CW1 indicated that Invacare would avoid giving full information in favor of just issuing a standard and meaningless non-committal clause so as not to give the FDA anything to work with.

71. Another former employee, CW2, was a Senior Reliability Engineer at Invacare in Ohio from approximately 2001 through 2006, and was tasked with verifying and validating

products and processes. CW2 stated that she was directly involved in the testing of the type of beds in question. CW2 stated that she headed the testing for several variations on the design of the Snubber Circuit, which is contained in the Control Box attached to the Invacare automated beds. CW2 stated that the type of bed units she worked with were of the same or very similar design to the ones at issue in the FDA's recent letter.

72. CW2 recalled that during her time at Invacare she became personally aware of an issue with the electrical design of Company's line of electric-powered beds, and specifically that certain components were overheating. CW2 stated that a component called a "snubber circuit" was located in the Control Box portions of the beds, on the underside of the beds. This "snubber circuit" was intended and designed to address the spike in voltage that occurred when the unit was activated. CW2 indicated that Invacare tried several versions of this "snubber circuit" system, including encasing it (as apparently also described by CW1 above) which exacerbated overheating issues. CW2 indicated that these overheating issues were an ongoing problem during CW2's tenure at Invacare. CW2 stated that she attended meetings where issues concerning a potential defect causing the overheating was discussed, as well as numerous discussions about the design and re-design of the snubber circuits.

73. Another former employee, CW3, worked at Invacare in various different sales and marketing positions for more than fifteen years, leaving in approximately 2005. CW3 worked with Invacare's hospital bed line and was familiar with the products at issue. CW3 stated that during her time at Invacare, it purchased electric motor components mostly from two companies with U.S. operations, Von-Wiese in St. Clair, Missouri and Linak, a world-renowned international motor company with a division in Louisville, Kentucky.

74. However, CW3 later heard that the Company was moving toward purchasing motor components from Chinese manufacturers instead, stating "I had heard with cost reductions and stuff like that -- [Invacare] had started to job-out sub-components. You know, you can get motors a whole lot cheaper by buying them in China in bulk." CW3 also reported hearing that Invacare had switched from producing bed-ends in its Mexican facility to instead buying them from Chinese manufacturers, and added: "So, the [difference in] dynamics of watching everything moving down your own production line versus opening the box to see what they [foreign suppliers] have just sent you is - everything."

75. CW3 also stated that in 2004, she had taken a position with another Invacare division (not working with beds) because the Company had all but dismantled its engineering group because "[they were] not going to waste any more money on original design on standard products anymore, and they basically took it to China."

76. Another former employee, CW4, was a Supervisor of Quality at the Sanford, Florida facility from the mid-1990s through approximately 2005. CW4 corroborated the existence of problems with respect to overheating related to the Control-Box in certain lines of the electronic bed products (specifically the home care beds), which she recalled had generated an FDA "Field Action."

77. CW4 recounted that during her tenure at the Sanford facility, the Company introduced a new type of motors for these beds, going "from using an AC motor or motors depending on the type of bed, with an electrical junction box that was designed by Invacare, to one that was higher assembly - manufactured by a third party." CW4 stated that "[t]hey designed the junction-box, and they designed the motors, and stuff like that. The reasons behind that change, was first a cost-savings measure, secondly, the problems with the junction-boxes -

there were cases of them smoking. And, the company did realize back then that there was potential for injury." Again, CW4 believed that this had resulted in an FDA "Field Action."

78. CW4 also corroborated the occurrence of the over-heating issues related to the encasement process, and recounted that the individual whom the Company held responsible for designing the encased Control Box had been fired after problems arose. CW4 stated that this resulted in the Company's decision to abandon its design-engineering division in Sanford, and "[i]t was shortly after they let [that employee] go, that they took all of the Design Engineering function and sent it all to corporate in Elyria for better control."

79. CW5 was an engineer in Sanford for over a decade, through approximately 2005, and worked extensively on Invacare's bed line products. CW5 recalled that overheating with the junction boxes or Control Boxes was an issue, and recalled that problems with the relays inside the boxes were causing the problems. CW5 also recalled that "[t]he potting process makes the box basically water-proof, but the problem lies within the box with the electrical relays, and I imagine it still is. They probably aren't potting them anymore, but the design is the same. I don't think that they went to a computer board, so it's got to still be relays."

80. CW5 also recalled that an engineer was terminated in connection with the development of the potting/encasement process, and that the attitude of the manager heading up quality assurance was adversarial, and with a poor work ethic, stating "I can imagine [that person's] attitude to a letter from the FDA - screw 'em!"

81. Another former employee, CW6, was a Supervisor in Invacare's Returns Department at the Sanford facility from 2002 through 2006. CW6 recalled that Invacare kept an area of its warehouse in Sanford designated as "Legal Area," and described it as "taped-off for

returned devices - tagged in red for legal" and stated that "(these devices) had to stay until the legal process was finished."

82. CW6 stated that overall returns totaled approximately 2-3 truckloads of materials a day, and that most of these were the company's Oxygen Concentrating units which had caught fire or melted, but CW6 recalled returns of burned beds and fire-related complaints relating to these beds. CW6 stated that many of these appeared to her to be user-generated, but she noted that the Company had been purchasing its junction box parts from a Chinese company, and that "[t]hese parts weren't top-grade" and "as soon as they started using that company -- a lot of stuff came back, and all of our parts were coming from [China] when I left." CW6 opined that these inferior parts may have been a cause of the overheating and fire-related problems.

83. CW7 was a mechanical engineer at Invacare from approximately 1995 through 2002, and held the title of Senior AutoCAD Drafter. CW7 stated that while she was technically on the mechanical side at Invacare, she also worked closely with team members on the electrical side.

84. Corroborating other CWs, CW7 recounted the issues with the Control Box of certain Invacare automated bed products, which she called the "brain." CW7 described the electrical system as one in which a remote control device plugs into a "control box" or "brain" on the bed, into which is also plugged a motor, which generates the bed's movement.

85. CW7 recalled that early on the Control Box was found to be not waterproof, which caused problems with the Control Box when it became wet. CW7 stated that these problems were also traced to a fault with the relay manufacturer. Invacare then re-designed the Control Box to be waterproof using a process called "potting," consisting of pouring plastic coating over the unit to provide a hard-plastic sealed waterproof encasement. However, this new

encasement design was causing or exacerbating an overheating problem with the relays inside the Control Box, leading to increased smoke-fire situations, and causing the relays to explode or catch fire within the potting.

86. CW7 also confirmed that Invacare fired one of its employees that it considered responsible for the re-design of the Control Box, in connection with these overheating/fire problems.

87. These witness observations and statements further confirm the long-running and pervasive issues at Invacare with respect to its safety, compliance, documentation and reporting policies and processes, including its woefully inadequate internal controls (or, perhaps more aptly, its lack thereof).

Invacare's Corporate Governance and Code of Ethics

88. In addition to its specific commitments to its products safety with regard to the FDA letter, Invacare displays on its website the Company's Code of Business Conduct and Ethics (the "Code"). The Code "covers a wide range of business practices and procedures," which if violated, will subject those employees to "disciplinary action up to and including termination of employment." The Code establishes the following key basic principles to guide its directors, officers and employees:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Full, fair, accurate, timely and understandable disclosure in the Company's annual and quarterly reports and in other public communications made by the Company;
- Compliance with applicable laws, rules and regulations; and
- The prompt internal reporting to an appropriate person or persons identified in this Code of Conduct of violations of the Code of Conduct and the underlying Company policies and procedures that

are incorporated into this Code of Conduct.

> Those who violate the Code of Conduct and/or any other Company policies will be subject to disciplinary action up to and including termination of employment.

89. The Code also emphasizes that "[o]beying the law, both in letter and in spirit, is the foundation on which this Company's ethical standards are built. All Directors, officers and employees must respect and obey the laws of the cities, states and countries in which we operate." The Code also encourages its employees to seek guidance when necessary because "[s]trict compliance with the law is mandatory."

90. The Code further states in regard to its business practices that "***[t]o maintain the Company's valuable reputation, compliance with our quality processes and safety requirements is essential.*** In the context of ethics, quality requires that our products and services be designed and manufactured to meet our obligations to customers. All inspections and testing documents must be handled in accordance with all applicable regulations."

91. The Company also maintains a Financial Code of Ethics to supplement its other policies and procedures, which specifically applies to the CEO, CFO, and principal accounting officer or controller. The Financial Code states that the Company "expects all of its employees to act with personal and professional integrity in all aspects of their employment, to comply with all applicable laws, rules and regulations, to deter wrongdoing" and Company policies and procedures. The Financial Code also requires compliance with applicable governmental laws, rules and regulations and "full, fair, accurate, timely and understandable disclosure" in reports to regulators and other public communications.

92. Invacare's Code of Ethics and Corporate Governance Guidelines and Financial Code of Ethics emphasize the Company's supposed commitment to the highest business standards both in relation to its shareholders and its customers and abiding by laws, rules and

regulations. The conduct described herein, including, e.g., the improper documentation of incidents with its products and how it has addressed these serious issues in violation of applicable laws and regulations, as well as the woefully inadequate and self-serving response to the FDA's findings and concerns, as described above, violates both the spirit and letter of the Company's Codes of Ethics.

DEFENDANTS' MISCONDUCT AND BREACHES OF FIDUCIARY DUTIES HAVE EXPOSED THE COMPANY TO SUBSTANTIAL HARM

93. The Individual Defendants owed and continue to owe the Company the duty to exercise a high degree of due care, loyalty, and diligence in the management and administration of the affairs of Invacare, including conducting its business in an ethical and legal manner. The conduct of Invacare's directors complained of herein involves a knowing and/or reckless violation of their obligations as directors of Invacare, which the Individual Defendants were aware and/or should have been aware posed a risk of serious injury to the Company.

94. The Individual Defendants, as officers and directors of Invacare, were and are required to exercise reasonable and prudent supervision over the management, policies, practices, controls, and financial affairs of the Company and the actions of its employees. The Individual Defendants were and are required, among other things:

a. To, in good faith, manage, conduct, supervise, and direct the business and affairs of Invacare carefully and prudently and in accordance with the laws and regulations of the U.S. and the state of Ohio, and legal and ethical business obligations;

b. To neither violate nor permit any other director, officer, or employee of Invacare to violate applicable federal and state laws, rules and regulations, or any rules or regulations of Invacare;

c. To remain informed as to the status of Invacare's business practices, and upon receipt of notice or information of improper, imprudent or unsound practices, to make a reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices and make proper disclosures;

d. To supervise the preparation, filing and/or dissemination of public filings, press releases, audits, reports or other information required by law or regulation, to examine and evaluate any reports or examinations, audits, or other financial information concerning the financial condition of Invacare;

e. To cause Invacare to obey and comply with and not violate applicable laws, rules, regulations and its own internal policies, rules and ethical guidelines;

f. To ensure that Invacare was operated in a diligent, honest and prudent manner in compliance with all applicable federal and state laws, rules and regulations; and

g. To maintain and implement an adequate system of controls and information systems, to ensure compliance with all federal and state rules and regulations, and guidelines, and internal rules, regulations, policies and guidelines, and such that no officer, director or employee of Invacare can or would make false statements about Invacare to the securities markets or to government agencies.

95. The Individual Defendants, as directors, owe Invacare the duties of due care and loyalty in the performance of their responsibilities with respect to Invacare's operations. Each Individual Defendant in this action, individually and/or jointly, as alleged herein, breached their

fiduciary duties to the Company by participating in, approving, and/or acquiescing in the misconduct and lack of internal controls and compliance safeguards herein, including, among other things, the improper training of Invacare employees, customer service representatives, the sales force, and other key contact employees regarding reporting of consumer complaints about its products, including major injuries and even death.

96. By reason of their membership on the Board and/or positions as executive officers of the Company, the Individual Defendants were each controlling persons of Invacare and had the power and influence to cause or prevent, and did cause or failed to prevent, Invacare to engage in and/or permit the conduct complained of and the circumstances and situation which existed (and still exists) at Invacare, as described herein.

97. As directors, and by reason of their control positions, the Individual Defendants owed Invacare fiduciary obligations of candor, fidelity, trust, and loyalty, and are and were required to use their ability to control Invacare in a fair, just and equitable manner, as well as to act in furtherance of the best interests of Invacare, and not in furtherance of their personal interests. In addition, each director owed Invacare the fiduciary duty to exercise due care and diligence in the management and administration of the affairs of Invacare and in the use and preservation of its property and assets.

98. The Board consciously failed to oversee the establishment of adequate internal controls and compliance procedures, including, *inter alia*, procedures for identifying training needs to ensure that all personnel are trained to adequately perform their assigned responsibilities and for documenting, tracking, and accurately reporting problems and injuries with its products and other wrongful and improper conduct in violation of their fiduciary duties. The Board, in breach of their fiduciary duties, permitted Invacare to conduct its business in an improper and

imprudent manner by failing to adequately document, track and report serious problems with its products, which has resulted in the FDA taking action against the Company, including issuing Warning Letters to the Company, and will likely result in further significant costs, liability, other lawsuits, harm, and other serious reputational and financial damage to the Company. The scheme has already undoubtedly caused a significant financial harm to the Company with expenses relating to the FDA investigation, not to mention the reputational harm the Company has already suffered as a result of the latest debacle resulting from the Defendants' failure to comply with their fiduciary duties for years.

99. Furthermore, rather than take advantage of FDA's latest (or its prior) investigations and warnings and recognizing them as an opportunity to take drastic steps to remedy the Company's improper policies, practices, procedures, and implement appropriate and effective internal controls and compliance mechanisms, the Individual Defendants, and the Company, chose to ignore the criticisms and allow the situation to worsen.

100. The Individual Defendants participated and/or acquiesced in the misconduct and egregious circumstances complained of herein, which exposed the Company to significant harm and potential liability. Such participation and/or acquiescence involved, among other things, participating, planning and creating (or permitting to be planned and created), and authorizing, approving and/or acquiescing in the acts and circumstances complained of herein. The alleged acts of wrongdoing are in violation of relevant laws, rules and regulations and have subjected (and continue to subject) Invacare to significant and unreasonable risks and harm without any commensurate or appropriate reward to the Company.

DERIVATIVE AND DEMAND ALLEGATIONS

101. Plaintiff brings this action derivatively in the right of and for the benefit of Invacare to redress injuries suffered and to be suffered by Invacare as a direct result of the

violations of law, breaches of fiduciary duty, corporate mismanagement, abuse of control, as well as the aiding and abetting thereof, by the officers and/or directors of Invacare.

102. Invacare is named as a nominal defendant solely in a derivative capacity.

103. Plaintiff will adequately and fairly represent the interests of Invacare in enforcing and prosecuting its rights.

104. Plaintiff has made every effort to obtain the action Plaintiff desires from the directors prior to instituting this action, to no avail.

Plaintiff's March 10, 2011 Demand Letter

105. In a detailed, ten-page demand letter dated March 10, 2011, Plaintiff set forth in its concerns about the recent events at Invacare, the harm suffered and faced by the Company as a result, and demanded that Invacare's Board of Directors institute this action against the Board and any other culpable parties for damages resulting from breaches of fiduciary duties owed by them to the Company. Plaintiff demanded that such action be taken within 45 days of receipt of the letter.

106. The Board (through its attorneys Calfee, Halter & Griswold LLP) replied over a month later on April 22, 2011 (ironically the same day that they announced Craven's abrupt resignation) with a letter attempting to stall. The April 22 letter was non-responsive, and failed to give any information or position on the Plaintiff's demand. Instead, the Board sought another six weeks until it would then purportedly be "able to give [Plaintiff] an update on the anticipated date of [its] response on or before June 15."

107. Plaintiff rejected these dilatory tactics, and responded by letter dated May 10, 2011, stating, *inter alia*, that "[t]he Board's non-committal response, coupled with recent news that Invacare's chief compliance officer vacated the position after a week on the job, exacerbates the concerns raised in our clients' initial demand letter." Plaintiff demanded a response by May

20, 2011, in the absence of which Plaintiff intended to "immediately commence a derivative action on behalf of the Company." Plaintiff's counsel also offered to discuss the matter prior to May 20, if Defendants' counsel so desired.

108. On May 16, 2011, the Board (again through counsel) replied that it would not respond by May 20, but that it had appointed a Special Committee of purportedly independent directors to investigate Plaintiff's demand. The May 16 letter stated that the investigation was under way but would not be complete until mid-July, 2011, and offered little else regarding the Committee's actions or the investigation of Plaintiff's demands. The May 16 letter did not identify the members of the Special Committee (nor does it appear that they have they been publicly identified to date). The letter also stated that Plaintiff would be contacted by the Special Committee's counsel requesting "information that the Special Committee believes will be quite helpful to its investigation."

Plaintiff's Cooperation Proposal

109. On May 23, 2011, at Plaintiff's counsel's request, Plaintiff's counsel held a conference call with attorneys from Jones Day, counsel for the anonymous (but supposedly independent) Special Committee. Plaintiff again expressed its concerns about the recent actions and findings by the FDA concerning Invacare's business practices and internal controls, and the Special Committee's delay in taking, and ability to take, necessary and appropriate action. Plaintiff questioned the independence and ability of these entities to do so, considering (among other things) that Plaintiff's recent investigation had uncovered evidence of persistent, serious and similar unresolved problems at the Company dating back many years.

110. During the May 23 teleconference, Plaintiff essentially voiced concerns that the current leadership at Invacare would not be willing and/or able to adequately address the issues facing the Company. To alleviate these concerns, Plaintiff proposed to work with the Special

Committee and/or the Board through a cooperative relationship to provide true independent oversight.

111. In a good faith effort to work together and avoid derivative litigation which would otherwise be necessary, Plaintiff proposed that it and its counsel be allowed to actively participate in the Special Committee's efforts to address and resolve the issues at the Company. Plaintiff proposed this as a reasonable compromise which would ensure a truly independent presence and voice in the process of addressing the issues and problems at Invacare.[7]

112. Plaintiff also offered to share the information gathered as a result of its investigation under the rubric of such a cooperative relationship, where it could be sure that the information would be used properly and kept confidential (e.g., to protect against the risk of any retaliatory actions against any of the CWs, former Invacare employees).

113. Initially, Defense counsel appeared receptive to such an arrangement, and requested that Plaintiff make a written cooperation proposal. Plaintiff agreed to do so. Since any such cooperation proposal was being made in an effort resolve a dispute and to avoid otherwise necessary derivative litigation, Plaintiff requested that it be kept confidential as settlement negotiations under Rules 408 of the Federal Rules of Evidence and the Ohio Rules of Evidence.

114. Plaintiff sent the written cooperation proposal (the "Cooperation Proposal") on June 3. 2011. Plaintiff again summarized its concerns, and discussed certain of its interviews with former employees. As Plaintiff had previously informed Defendants it would do, Plaintiff outlined basic information requests so as to further assess and address the Company's safety and

[7] Plaintiff noted that this type of cooperation has been successfully instituted in other derivative litigations, provided an example, and offered to provide others.

maintenance procedures and corporate governance issues. Following up on the prior teleconference, Plaintiff reiterated its cooperation proposal and:

> propose[d] to assist the Special Committee to ensure that processes are put in place to address the serious issues identified by the FDA, and that these processes are independently created and implemented. To accomplish this, we would need to be fully informed of the Special Committee's investigation with regular updates through written communications, or telephonic or in-person meetings, and to be involved with preparing and drafting any reports regarding the findings of the investigation. As we mentioned previously, we and our clients have engaged in a similar capacity with special committees in the past, resulting in significant benefits and stronger corporate governance for the companies involved. We hope to be able to do so with to Invacare as well.

Defendants' Grossly Mischaracterize the Plain Terms of Plaintiff's Cooperation Proposal, and then Reject it Without Explanation

115. The Special Committee (through counsel Jones Day) responded to Plaintiff's Cooperation Proposal, with an adversarial letter dated June 13, 2011. The Special Committee's response made it apparent that the Defendants' had engaged in earlier discussions as a subterfuge to get Plaintiff to let down its guard and reveal its investigative materials, and that the Special Committee never seriously considered or had any real intention of working cooperatively under any circumstances.

116. The Special Committee essentially responded as if there had been no discussion of Plaintiff's concerns about ensuring truly independent oversight of the process of addressing the problems at Invacare or of a reasonable cooperation proposal. The Committee instead demanded that any cooperation or information sharing be a one-way street, completely in favor of the Defendants. While demanding that Plaintiff and its counsel open their investigative files, the Special Committee refused to reciprocate or share any of the basic information Plaintiff had requested (with one very minor exception). The Committee offered only the conclusory justification that "they are neither necessary or proper for providing to you in the current context."

117. The Committee then rejected any cooperation with Plaintiff or its counsel with the equally conclusory statement that "it has the necessary resources to examine, consider and report on the matters in question," and the false and conclusory assertion that "your involvement in the evaluative process would be [neither] necessary nor productive." Defendants offered no explanation for the fact that despite the fact that the Board has apparently failed to address, much less resolve, these outstanding issues for years now.

118. After refusing to cooperate or work together at all, the June 13 letter tersely demanded that Plaintiff's investigative information be provided "promptly," and that "if we do not hear back from you within seven days of the date" it would assume that no such information would be provided. The letter did not stop there, however, and, while unwilling to provide any information requested by Plaintiff, the Special Committee demanded more information from Plaintiff concerning its Invacare investment (Plaintiff had previously provided proof of ownership with its initial demand letter).

119. Although these communications were obviously taking place in the context of Plaintiff's intention to bring a derivative lawsuit if actions were not commenced by the Board, the June 13 letter rejected Plaintiff's request that the communications be treated confidentially as settlement negotiations, and the Special Committee pretended not to understand why such confidential treatment would be applicable at all.

120. Defendants' refusal to consider any cooperation proposal only applied to themselves, of course; they demanded and expected full cooperation from Plaintiff and its counsel with no reciprocation, and again pretended that the terms of the Cooperation Proposal were different than they were. The Special Committee ignored the plain language of Plaintiff's June 3 letter stating that "[i]n return for the above-requested information, we agree to share

information gathered in the course of our investigation (the 'Investigative Information') . . .," and somehow bizarrely concluded that it should "not read [Plaintiff's] June 3 letter as conditioning your willingness to provide the information sought by the Committee on your firm's being invited to became an actual participant in the Committee's work . . ., or on the Committee's providing the internal information cited in your letter."

121. Accordingly, the Board and the Special Committee have failed to act in good faith, and completely ignored both the prior discussion and the unambiguous terms of the Plaintiff's Cooperation Proposal. In light of the Board's and the Special Committee's conduct, and its failure to timely or adequately respond to Plaintiff's demand, Plaintiff chose not to respond to Defendants' June 13 letter and continued its investigation with the intent of filing the instant action.

Defendants' Reject Plaintiff's Demand for Action But Concede that the Company's Internal Controls and Safeguards were and are Grossly Inadequate Requiring Significant Remedial Measures

122. On July 18, 2011, Defendants rejected Plaintiff's demand for action. The Board supposedly based this rejection on the anonymous but purportedly "independent" Special Committee's report and recommendation. The Board rejection was based on conclusory and erroneous findings and vague and/or distorted reasoning, that, among other things, the claims Plaintiff demanded be brought had no basis, the Company had suffered no material damages, and the costs of pursuing litigation would purportedly outweigh the benefits of doing so.

123. In the same letter, however, the Board essentially conceded that the Company's internal controls and compliance practices under their own watch were seriously flawed and inadequate (at a minimum). As a consequence, the Committee had even "recommended that the Company take further actions" to remedy shortcomings in (in the Board's euphemism, "enhance") its internal controls and compliance safeguards. These "further actions" included:

- "Utilizing specialized counsel and external consultants to assist the Company's personnel with FDA compliance";
- "Having internal audit, specialized personnel within the regulatory function, external consultants, or other qualified personnel within the Company, regularly audit the Company's FDA compliance efforts (as Internal Audit has presently undertaken regarding [MDR] filings)";
- "Continuing the search for appropriate senior-level individual(s) to oversee regulatory and health care industry compliance";
- "Open[ing] discussions between the Board and management to enhance the efforts of the Management Review Team beyond oversight of the Product Safety Committee or, alternatively, forming a Compliance Committee within management to oversee FDA and broader compliance issues";
- Expanding on specialized training opportunities (healthcare and FDA compliance) to a broader group of Company employees"; and
- "Standardizing its compliance procedures across Company facilities."

124. Even if the Board was sincere about these actions and instituting real change at Invacare, it has conceded that these changes will have come about only and directly as a result of Plaintiff's intervention and demand upon the Company. The Board and the Special Committee have already stated that the Special Committee was only created as a result of the Plaintiff's March 10 demand,[8] and that, in turn, the supposed remedial measures listed above were

[8] See the Board's May 16, 2011 letter at p. 1 (" . . . the Board is working thoroughly to investigate the claims made in your letter. The Board has appointed a Special Committee . . . [advised by Jones Day] to conduct the investigation . . ."). and the Special Committee's June 13, 2011 letter at p. 2 ("[T]he demand that has prompted the Committee's formation and activity was made on behalf of your client.").

recommended as necessary by the Committee as a result of the investigation prompted by the Plaintiff's demand.[9]

125. Although it had Plaintiff's demand for over five months, the company has apparently never once disclosed to its shareholders or the investing public obviously material information relating to the Plaintiff's demand, including (a) the existence of the demand; (b) the fact that the Board established a Special Committee to address the demand, and the Committee's supposedly months-long investigation, report and recommendations; or (c) the supposed changes recommended by the Special Committee.

126. The failure to disclose this material information is further evidence of the highly insular and dysfunctional culture at Invacare, and the Board's disregard for the interests and welfare of the Company (and its shareholders).

127. Plaintiff's allegations and the misconduct outlined herein raise a reasonable doubt that the Board's decision to reject the demand was the product of a valid business judgment. The Board's failure to bring the demanded action against culpable individuals for breaches of their fiduciary duties, as well as, *inter alia*, their failure to sufficiently investigate these breaches, constitutes a wrongful, unreasonable and improper refusal.

128. Based on the foregoing, Plaintiff has standing to institute the instant derivative action.

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[9] See the Board's July 18, 2011 letter at p. 5 ("Although the Committee recommended against litigation, it found through its investigation other areas where the Company should take action. . . .")

COUNT I

Breaches of Fiduciary Duties Against Individual Defendants

129. Plaintiff incorporates by reference each of the foregoing allegations as if fully stated herein.

130. The Individual Defendants are fiduciaries of Invacare and owe to it the duty to conduct the business of the Company loyally and with due care. This cause of action is asserted based upon Invacare and its employees' acts in violation of federal and state law, which acts were approved of or consciously ignored by the Individual Defendants, and which constitute breaches of fiduciary duties.

131. The Individual Defendants have been responsible for Invacare's misconduct because they abdicated their corporate responsibilities and breached fiduciary duties, including those of care, candor and loyalty:

a. They allowed and participated in a scheme to improperly report and address problems with its products;

b. They concealed in SEC filings the true nature and workings and lack of internal reporting procedures of the Company's business from shareholders;

c. Even after the FDA investigation revealed Invacare's improper reporting of problems with its products, Invacare failed to sufficiently respond to the FDA's concerns, and upon receiving the 2010 Warning Letter has tried to falsely distance itself from it by claiming, *inter alia*, that the 2010 Warning Letter did not relate to the safety of its products, and any expenses associated with it would be immaterial. As demonstrated above, this was contrary to the FDA's allegations in its warning letter.

d. They subjected Invacare to adverse publicity and severe reputational harm and potential legal liability that has already caused expense from the FDA investigation and threatens to interrupt approval of future products, awards of contracts and lead to even further liability.

132. As a direct and proximate result of the Individual Defendants' breaches of duty alleged herein, Invacare has sustained and will continue to sustain significant damages.

133. The Individual Defendants conspired to abuse, and did abuse, the control vested in them by virtue of their positions in the Company.

134. By reason of the foregoing, the Individual Defendants have breached their fiduciary obligations to Invacare.

135. Invacare has been injured by reason of the Individual Defendants' intentional breach and/or conscious disregard of their fiduciary duties to the Company. Plaintiff, as a shareholder representative of Invacare, seeks damages and other relief for the Company as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment on behalf of Invacare as follows:

(1) Determining that this action is a proper derivative action maintainable under law and demand is wrongfully refused;

(2) Against each Individual Defendant for restitution and/or damages in favor of Plaintiff, on behalf of Invacare;

(3) Extraordinary equitable and/or injunctive relief as permitted by law, equity and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on or otherwise restricting the proceeds of Individual Defendants' trading

activities or their other assets so as to assure that Plaintiff on behalf of Invacare has an effective remedy;

(4) Removing each of the Individual Defendants from the Board of Directors;

(5) Awarding Plaintiff the costs and disbursements of this action and related to its demand, including reasonable attorneys', accountants', and experts' fees; and

(6) Granting such other and further relief as this Court may deem just and proper.

Dated: August 23, 2011

Respectfully submitted,

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James B. Rosenthal (0062872)
jbr@crklaw.com
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777 Woodward Avenue, Suite 890
Detroit, Michigan 48226
(313) 309-1760

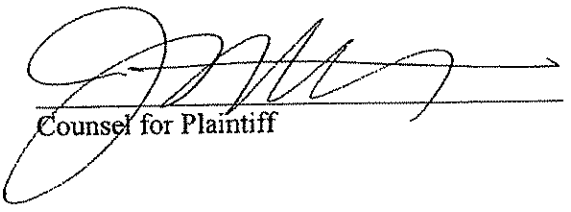
Counsel for Plaintiff

Of Counsel:
Brigham Smith
OFFICE OF THE CITY ATTORNEY
124 West Michigan Avenue
Lansing, Michigan 48933
(517) 483-4320

Counsel for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury of all issues so triable.



Counsel for Plaintiff

VERIFICATION

I, BRIGHAM SMITH, City Attorney of the City of Lansing,on behalf of Plaintiff City of Lansing Police & Fire Retirement System, having been duly sworn, hereby depose and state that I have read the foregoing Verified Derivative Complaint and that the information stated therein as factual is true, and those factual matters which are stated upon information and belief are believed to be true.

Brigham Smith

Subscribed to and sworn before me this 23 day of August, 2011

Notary Public

CHRIS SWOPE
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF INGHAM
My Commission Expires Sept. 5, 2012
Acting in the County of Ingham

EXHIBIT 1

Public Health Service d20076

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-69

August 20, 1998

A. Malachi Mixon, President
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036

Dear Mr. Mixon:

We are writing to you because on July 22, 1998, FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving electric patient beds, lift out chairs, and adjustable, automatic air mattresses, which are manufactured and distributed by your firm in Sanford, Florida.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

- Failure to validate and document significant manufacturing processes and quality assurance tests to assure specific requirements are met, e.g., robot and manual welding processes, and software used to program the chip in the control device of the automatic air mattress.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #1 is inadequate because no documentation of the software validation was provided or available to the investigator for his review, nor is it provided in the response. We do not believe there was any miscommunication, since the investigator requested to see the software documentation used to program the chip for controlling the device and none was available according to your firm's Quality Manager (QM). Your firm's response also addresses the validation that will be conducted covering the welding processes. Please provide copies of the completed validation runs for our review and file. Pending our review of this documentation we will verify this corrective action during the next inspection of your firm.

- Failure to establish and maintain device history records (DHR's) demonstrating devices are manufactured and tested in accordance with the DMR and other requirements of the QS regulation, e.g., there are no DHR's for the manufacture of the electric beds and lift out chairs.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #2 is inadequate because your Quality Manager (QM) stated during the inspection that there are no records of finished product inspection or release for distribution. He said the only record kept was of the serial numbers used, which identify the production number and date of manufacture. The blank copy of the record attached to your firm's response is not adequate for us to review and make a determination of your firm's compliance with this regulation. Please provide copies of testing records covering the months of May and June for our review and files. This item will require verification during the next inspection of your facility.

- Failure to establish and maintain procedures for implementing corrective and preventive actions, e.g., there are no procedures and/or documentation ensuring that the actions taken are effective and do not adversely affect the finished device; and that information is disseminated to those directly reponsible for assuring the quality of such product or the prevention of such problems.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #3 is inadequate because your QM stated that audits of returns and complaints were conducted a month later to determine if evidence of the failure mode still existed. As was explained during the inspection, all corrective actions require verification or validation prior to release of the device to distribution. Further, your QM stated that no verification or validation of a corrective action is conducted, and there is no documentation covering these activities.

Your QM also stated that there are no provisions in your written procedures to ensure that this sort of information is adequately disseminated to those directly responsible for quality issues. He said individuals other than himself may or may not receive the information.

We don't know of any miscommunication with regard to this observation. We feel after review of the documentation collected during the inspection and statements by the QM that our understanding of this issue is clear. Our review of BB14-001 does not show that corrective actions are routed to all responsible individuals and management for their approval and sign-off prior to implementation. In fact, BB14-001 provided with the response is not signed off by any of the management listed on page one of the procedure, which shows a revision date of 6/30/98.

- Failure to establish procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned responsiblities and that all training is documented, e.g., your QM stated that he had no formal training in GMP's, the QS regulation, process validation, design control and other areas that a person in this position would be required to manage. Your QM stated that he had a one day course in ISO 9000 which was documented, and was scheduled to attend a 2 day course on process validation.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #4 is inadequate because the response fails to address the QM's lack of specific training for the responsibilities for which he has authority. The QM is obviously qualified for the position he holds and no one is disputing that, however, he obviously has received little training dealing specifically with the areas that he is directly responsible for supervising including: process validation, design control as it relates to manufacturing, finished device testing, corrective and preventive actions, failure investigations, complaint handling etc. Without documentation of these activities, there is no way for FDA to determine a person's ability to adequatley manage and supervise. Your response states that all employee training will be conducted and documented. This observation will be verified during the next inspection of your firm.

- Failure to include and implement written procedures to define and identify returns as complaints, to review and evaluate all complaints including returns to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803 or 804, and to assure failure investigations and corrective and preventive actions are conducted and documented, e.g., according to documentation collected by the investigator, your firm collects some data conducts trend analysis of product returns, however, the QM stated that investigations are not conducted and documented pursuant to a procedure to make the determinations noted above.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #5 appears to be adequate and will be verified during the next inspection of your firm.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administratrion without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the timeframes within which the corrections will be completed, (2) any documentation indicating the correction has been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District

EXHIBIT 2

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Invacare Corporation 26-Aug-03

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

August 26, 2003

Via Federal Expres

WARNING LETTER
CIN-WL-03-15559

Aaron Malachi Mixon, Chairman &
Chief Executive Officer
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036

Dear Mr. Mixon:

Investigators from the Food and Drug Administration (FDA) inspected your firm?s facilities located at 1200 Taylor Street, 899 Cleveland Street, and One Invacare Way in Elyria, Ohio, between March 10 and 25, 2003. This inspection revealed that the medical devices your firm manufactures, such as power wheelchairs and power scooters are adulterated within the meaning of Section 501 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820 (QSR) as follows:

1. Failure to establish and maintain adequate procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

For example, the [redacted] fuseholders used with [redacted] wire in the battery box assemblies were used in an application that was outside of the manufacturer?s recommended specifications for these components without adequate validation or verification of this design change based on the application in which these components were used.? Specifically, your firm did not adequately validate the ability of the [redacted] fuseholder with [redacted] wire to safely handle current levels above the specified 10 amp rating under normal operating conditions, which wil lead to higher operating temperatures.? Also, your firm did not adequately validate the ability of the [redacted] fuseholder with [redacted] wire to be safely used in an environment subject to vibration.

In addition, testing that was performed on the wire/fuse/fuseholder assembly was not completed until after these components were used in production.

In another example, the main fuse in the battery box assembly was changed from a 60 amp fuse to an 80 amp fuse with use of a [redacted] wir (per ECN 9903313). The tests performed to study the effects of the 75 - 80 amp DC current on the [redacted] wire were not completed until after the effective manufacturing date of September 7, 1999. The 80 amp fuse and [redacted] wire assembly is used in an application for which it operates at current levels above its rating for short periods of time under the normal operation of the wheelchair and potentially over much longer intervals in the event of a malfunction of a motor or, the control system.

Your firm did not adequately validate the ability of the [redacted] wire to handle operation above its rating. Engineering tests were conducted to verify that the wire insulation was not damaged when subjected to temperature stresses in a lab setting. However, the ability of the [redacted] wire to handle the increased current was not validated for its intended use because the testing your firm performed does not reflect the actual conditions in which this assembly is used (e.g., connected to a battery inside the battery box installed in a wheelchair).

2. Failure to have a complaint procedure that ensures that all complaints involving the possible failure of a device to meet any of its specifications are adequately reviewed, evaluated, and investigated, as required by 21 C.F.R. 820.198(c).

The FDA Investigator reviewed all of the complaints pertaining to alleged fire-related incidents that Invacare received from October 1, 2002 tc March 10, 2003. The majority of these 41 complaints involved smoking caused by a faulty gearbox seal. There was no documentation to show that Invacare investigated and evaluated these complaints to determine whether the smoking gearboxes are a safety concern.

3. Failure to establish and maintain adequate procedures for in-process acceptance activities including inspections, tests, or other verification activities to ensure that specified requirements for in-process product are met, as required by 21 CFR 820.80(c).

For example, the FDA Investigator observed that an assembler was performing in-process testing of sub-assembly #TS1079992, which is used in manufacturing power wheelchairs. This testing was not performed according to a written procedure, and the test results were not documented.

We acknowledge receipt of Invacare?s letters of response dated March 31, 2003, May 9, 2003 (a fax to the FDA Investigator), May 15, 2003, May 20, 2003, and May 21, 2003. In addition, we had a telephone conversation with Invacare representatives on May 14, 2003, during which some of the deficiencies were discussed.

The actions Invacare has taken appear adequate to correct some, but not all, of the deficiencies FDA observed during these inspections. We consider Invacare?s responses to be inadequate in the areas identified below.

With regard to item 1 above (FDA 483 observation #3), invacare responded in a letter dated March 31, 2003, that ?The actual problem identified here was that such testing and qualification, though done before implementation of the fuse holder back in 2000, was not documented.? As Invacare?s March 31st letter acknowledges, documented testing was not performed until several months after the fuseholder had been put into use. In responses dated May 15, 2003 and May 20, 2003, Invacare stated that the manufacturer?s recommendations are base upon a continuous load condition and users are instructed to check the requirements based on the specific applications. According to Invacare? responses, tests were performed to verify that the wire gauge size and fuseholder range are adequate for Invacare?s specific application. Invacare acknowledged, however, that there were four reports regarding heat deformity and melting of the [redacted] fuseholders. The

damaged samples were examined by an outside consultant, [redacted] Invacare stated that the report by [redacted] verifies the use of the [redacted] fuseholder for your application, and that Invacare subsequently decided to switch to a new fuseholder (via ECN #0303057) for use in production in April 2003. The reason stated for this switch was for reliability reasons.

The responses to this issue are inadequate because Invacare has not provided sufficient information regarding the corrective and preventive actions taken to address the root cause and failure mode of the reported heat deformity and melting of the [redacted] fuseholders. Although the report by [redacted] does not consider the incidents of heat deformity and melting of these fuseholders to be a fire hazard, the report does present a potential cause for these incidents. According to the report, vibration may cause weakening of the electrical connection between the fuseholder receptor and the stranded [redacted] wire, which in turn will cause heating under load and certain ambient conditions. It does not appear that Invacare has conducted additional testing to confirm this potential failure mode and to determine the actual root cause and failure mode.

Invacare also has not provided adequate information regarding the corrective and preventive actions taken to address powered wheelchairs that have the [redacted] fuseholders used with the [redacted] wire that are still in commercial distribution. In reference to the heat deformity and melting of the [redacted] your firm states in its letter dated May 15, 2003, that ?though there was no perceived safety hazard, Invacare chose to change to a different fuseholder.? However, our review of the information and data provided for the damaged [redacted] fuseholders indicates there may be a potential safety hazard. At least three potential reasons can be identified for the increase of the temperature of the fuseholder/wire electrical contacts: 1) this combination of components is being used at an operating current above its rating; 2) the inherent vibration in this application weakens the physical contact thereby reducing the effective cross sectional area of the electrical contact and increasing its electrical resistance; and 3) the oxidation rate of the contact metals is hastened with the deformation of insulation due to vibration, further reducing the effective contact area and further increasing electrical resistance. Melting and distortion of the fuseholder insulation without blowing the fuse indicate that the fuseholder has failed to perform its intended safety function and has the potential for becoming dismembered. Your firm did not demonstrate that the fuse in one of these melted and distorted fuseholders would eventually open (blow) before a source of electrical ignition (hot spot or electrical arc) could develop at the first physical separation of one of its electrical contacts from the conductor.

With regard to the 80 amp fuse and [redacted] wire assembly, the May 15, 2003 and May 20, 2003 responses indicate that an 80 amp current through this assembly is only sustained for a short period of time. Invacare states that a continuous 80 amp current would not be sustained because the controller software is designed to prevent this condition by limiting the current. Invacare states that if the controller software failed the controller would shut down with such a continuous load; however, Invacare has not provided adequate validation that the controller would function in this manner. The reports by [redacted] and [redacted] state that the highest temporary current from the battery is 130 amps when the motors are in a stalled condition. This current is only drawn for about 7 seconds after which the controller limits the current to 75 amps. [redacted] suggested that tests be performed to confirm that the 80 amp fuse would trip before the thermal limit of the [redacted] wire is reached, if the controller failed to limit the 130 amp current within the 7 second time limit. Invacare has not provided adequate validation that the 80 amp fuse would trip before the thermal limit of the [redacted] wire is reached if the controller failed to limit the 130 amp current within the 7 second time limit per [redacted] recommendation.

As was mentioned on page 2 of this letter, the testing that Invacare has performed does not appear to adequately demonstrate that the [redacted] wire can withstand a continuous 80 amp in the event of a controller failure. Hence, we believe that your firm?s wheelchairs have not been adequately validated for their intended use. The testing that has been provided does not show that Invacare has sufficiently addressed all of the possible effects of the [redacted] wire carrying an 80 amp current until the battery is discharged, including possible effects on other materials or patient in this type of environment. For example, the battery box may provide some thermal insulation such that the [redacted] conductor may experience significantly higher temperatures inside the battery box resulting in possible deformation inside the battery box, and other nearby components could be negatively impacted. Your testing ([redacted] report, pages 2-3) appears to show that the [redacted] conductor can tolerate temperatures up to 255? F (124? C) continuously over its rating with no damage to the wire; however, it does not appear that simulated use testing that addresses using an 80 amp continuous current with a battery harness in place in a wheelchair has been conducted, nor has an adequate justification been provided for not validating this simulated use condition. In addition, the criteria for determining damage to the wire were not documented in the test results. A test in a temperature chamber at 320? F for 30 minutes reported that no damage occurred to the harness. On the other hand the same report stated that the harness became more soft and flexible. Another report stated that the heat shrink material used to bind the wires in the wiring harness together had become soft, some of it had split, and the PTO connector had become soft and pliable.

A loss of insulating qualities can be determined by conducting a dielectric breakdown test as specified in recognized safety standards such as IEC 60601-1 and UL 2601. Invacare has not indicated that any such tests or equivalent tests were conducted.

With regard to item 2 above (FDA 483 observation #2), Invacare?s response letter dated March 31, 2003 discussed the steps being taken to correct the deficiency noted regarding the evaluation of complaints involving the possible failure of a device to meet specifications. Whereas Invacare stated that a new procedure would be implemented in April 2003 to describe the process to be followed for such assessments, there was no indication that Invacare plans to perform a safety assessment for the complaints identified by the FDA Investigator regarding power wheelchairs that were smoking due to a gearbox seal leak.

With regard to item 3 above (FDA 483 observation #4), Invacare?s March 31, 2003 letter indicated that your firm plans to review all in-process testing or checks to see which ones are effective in identifying problems early in the assembly process and that you will ensure that those identified as worth keeping are properly described in a procedure and documented. The letter further stated that this review may take until year end to complete. However, there was no indication that Invacare would make an assessment of any corrective actions needed for the products that were produced without testing according to a written procedure and for which there was no documentation that the in-process testing was performed.

Invacare should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies will be advised of the issuance of this warning letter so that they may take this information into account when awarding government contracts.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to Evelyn D. Forney, Compliance Officer, at the above letterhead address.

Sincerely,
/s/
Carol A. Heppe
District Director
Cincinnati District

Links on this page:

EXHIBIT 3

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Invacare Corporation 12/15/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751
Telephone: 407-475-4700
FAX: 407-475-4770

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-11-10
December 15, 2010

A. Malachi Mixon, III,
Chairman of the Board and
Chief Executive Officer
Invacare Corporation
One Invacare Way
Elyria, Ohio 44035

Dear Mr. Mixon:

During an inspection of your firm located in Sanford, Florida on August 2, 2010 through August 18, 2010, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures manual, electric, and semi-electric beds. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. We received a response from Ronald J. Clines, Director Regulatory Affairs and Corporate Quality Systems dated September 8, 2010, concerning our Investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems and to employ appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 CFF 820.100(a)(1). For example, your firm failed to analyze MDRs, adverse events, or product complaints during trend analysis by problem codes including those for entrapment and potential fire hazard.

Your firm's response dated September 8, 2010, is not adequate. Your firm has stated that you are investigating ways of improving trending of more serious allegations such as entrapment and fire risk. Your firm further stated that complaints of this type are trended during Product Safety Committee meetings which are held on a quarterly basis at a minimum. According to your firm's CAPA procedure, BB14-001, Quality Assurance analyzes these complaints and quality data to detect trends in failures requiring corrective action. Your firm's procedure does not however clearly identify the requirements for analyzing complaints or discuss what statistical methodology will be utilized to detect recurring problems which is a requirement under 21 CFR 820.100(a)(1). In addition, your firm has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

2. Failure to establish and maintain adequate procedures to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example, Section 5.1.1.1 of your firm's Corrective and Prevention Action procedure, BBI4-001, states, "Nonconformances that are repeating problems (trends) ...require documented evidence of corrective action." Additionally, Sec's 5.3, 5.4 and 5.5 of your firm's Customer Complaints procedure, BB14-002, states, "Quality Assurance designee ... reviews the investigation as well as corrective/preventive action documented to determine the appropriateness of the same. Upon completion of the failure investigation and determination of the corrective/preventive action, the results will be reviewed with the Quality Manager. Completed Inspection Repoi Forms are reviewed and approved by Quality Assurance Manager... "

However, recurring complaints relating to potential sparks/fires associated with the beds did not contain a documented determination of the action(s) needed to correct and prevent recurrence of the nonconformances, such as:

a) Complaint # 5426 dated July 26, 2010, references a user who alleges the device was sparking when the pendant was plugged in.

b) Complaint # 5208 received June 25, 2010, references a driver set-up an Invacare bariatric bed and found no power to the bed. A burning smell was noted but no actual smoke.

c) Complaint #4894 received June 2, 2010, references the junction (control) box of an Invacare bariatric bed caught fire and two patients were taken to the hospital and treated for smoke inhalation and chest pain. Visible flames were observed, however when the unit was unplugged the fire went out.

d) Complaint #4521 received April 13, 2010, references a fire started at the foot of an Invacare bed (model # unknown) resulting in a consumer's death.

Additionally, the following complaints relating to entrapment with the use of your firm's bed rails did not contain a documented determination of the action(s) needed to correct and prevent recurrence of the nonconformances, such as:

a) Complaint #4234 dated February 17, 2010, references that there was an alleged death of patient and entrapment with Invacare bed betwee the bottom of the rail and the top of the mattress. It is documented in your firm's investigation that health care facility personnel stated a coroner's report indicated that the patient suffered a heart attack and then was allegedly entrapped post mortem.

b) Complaint #4181 received February 11, 2010, references a consumer that alleges an Invacare bed system allowed his wife's head to get stuck between the rail and mattress causing her suffocation.

Your firm's response dated September 8, 2010, is not adequate. Although your firm stated you have taken actions to increase awareness to your customers and users regarding entrapment, you also stated they were incremental in nature and were not to correct any identified product defect of malfunction. Your firm also stated moving forward, you will continue to examine entrapment risks and is considering adding additional instruction regarding body size as it may relate to increased entrapment. However your firm's response did not discuss or provide any evidence of their process for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems. In addition, your firm has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

3. Failure to maintain an adequate record of the investigation including the dates and results of the investigation, as required by 21 CFR 820.198(e). For example, complaints received by your firm did not include an adequate written record of the dates and results of the investigation, such as:

a) Complaint #4894 received June 2, 2010, references that the junction (control) box of an Invacare bariatric bed caught fire and two patients were taken to the hospital and treated for smoke inhalation and chest pain.

b) Complaint #4522 received April 13, 2010, references an Invacare bed and bed rail that was allegedly involved in a bed entrapment death of a child (age 11).

Your firm's response dated September 8, 2010, is not adequate. Your firm has stated you reviewed your current complaint investigation process and although not specified, are exploring solutions that would document and define "Critical Information" requirements and the attempts to gather this information. Your firm has stated that these corrective actions would be completed by October 15, 2010; however, you have not provided any evidenc of implementation of changes to the current investigation process. Your firm also stated you documented a risk assessment specifically to the potentia fire issue and will submit it to FDA by October 15,2010. Your firm also provided updates on several of the complaints mentioned in this observation, which included additional information you received from your investigation or the status of pending information. You further stated you would like improvement on how investigations are documented especially with regard to information that Invacare requests but is not provided or denied. Although you state that many complaints involve product that has been in rental fleet for years, the history is unknown, or the provider has no information regarding the product use, you did not mention how you will ensure that the dates and results of complaint investigations are adequate. Additionally, your firm did not discuss how you will conduct a systemic corrective action that involves re-assessing all complaints to ensure that the investigations were adequately completed and documented

4. Failure to establish and maintain adequate procedures for validating the device design in order to ensure that devices conform to defined user need and intended uses, and perform risk analysis where appropriate, as required by 21 CFR 820.30(g). For example, Section 7.8 and 7.9 of your firm's procedure, CP04-013, for Risk and Hazard Assessment Process states, "If information is obtained from production or post-production activities that suggests the existing risk assessment may not reflect current information, this information is assessed to determine if a need exists to modify the existing risk assessment. The Risk and Hazard Peer Review will address ...Have risk been estimated for each identified hazard? Are the risk acceptable (i.e ... will misuse increase the likelihood of failure, etc.?" Additionally, Sec 8.1.1 states that in using the risk assessment form, the following device characteristics at a minimum are to be considered for each corresponding section, "device or component failure (special intervention) ... user operatio requirement (instructions for use/maintenance) ... device interaction with other devices/substance".

However your firm has failed to update the risk analysis for the Invacare bed systems with the following post-production information:

a) Risk of entrapment associated with the firm's bed systems including but not limited to non- Invacare mattresses/bed rails or use with smaller size patients except for CS (Carroll Series) Long Term Care Bed Systems, whose formal risk analysis does include patient entrapment issue but also does not include use of devices by smaller size patients.

b) Risk assessment concerning Echo, Arro, and CS Invacare Beds with all Invacare mattresses including but not limited to models # 5180, 5184 and 5185.

c) Risk of improper installation of bed rails for the bed systems except for CS (Carroll Series) Long Term Care Bed Systems.

d) Risk Assessment for warning label that was used on Invacare model # 5185 mattresses in order to reduce risk of entrapment on August 1, 2007, however the investigator was informed that the firm stopped using this label on model # 5185 mattresses on February 21, 2008. The firm stated they believed it was redundant since the same information was being included in instructions for use for full length bed rails (released on December 6, 2007). In addition, the firm did not document when the new instructions for use were initially distributed with the product.

Your firm's response dated September 8, 2010, is not adequate. Your firm has stated that you will conduct a risk assessment regarding bed rail entrapment with the intent of determining if the areas of concern that are not currently addressed, such as patient size, or if existing labeling can be augmented in some way. Your firm also stated that these activities will be completed by October 30, 2010; however, you have not provided any evidence of implementation of this corrective action. Your firm further stated that risk assessment is conducted as part of the product development

process and as part of the complaint handling process when malfunctions are identified. In addition, you stated that you have been proactive in addressing bed rail entrapment risk before the FDA guidance document in March 2006. However your firm's response did not address other issues associated with the mattresses or bed rails or how, according to your procedure, CP04-013, information obtained from production or post-production activities that suggests the existing risk assessment may not reflect current information will be assessed to determine if a need exists to modify the existing risk assessment. Additionally, your firm did not discuss how you will conduct a systemic corrective action that includes a retrospective review and reevaluation of other types of complaints to ensure that the risk analysis has been appropriately updated.

5. Failure to establish adequate procedures for identifying training needs for ensuring that all personnel are trained to adequately perform their assigned responsibilities and for documenting training, as required by 21 CFR 820.25(b). For example, Sec 3.2.6 of your firm's Complaint Handing and Medical Device/Vigilance Reporting Procedure, CP14-002 states Customer Affairs, "Provides training to new customer service representatives regarding Adverse Event complaints and current methods for reporting quality problems and incidents. Training may also be provided to the sales force or other key contact employees when appropriate". Section 3.32 further states Regulatory Affairs "Reviews previous complaint history, FDA Maude database, o previous FDA MDR database to review previous related incidents for similarities or trends...Updates. the complaint database system with analysis data inspection status and material location as required."

a) However, a review of the training of customer service personnel showed no documentation that the following customer service personnel have ever received training on the firm's complaint handling procedures although they received at least the following complaints:

(b)(6) (File # 2837 dated June 24, 2009), **(b)(6)**(File # 3490 dated September 21, 2009), **(b)(6)** (File # 4152 dated February 1, 2010) and **(b)(6)** (File # 4181 dated February 11, 2010).

b) The following Invacare customer service personnel also took part in complaint handling activities prior to obtaining documented training on complaint handling:

(b)(6) (# 2045 dated February 9, 2009), **(b)(6)** (File # 2267 dated February 23, 2009), **(b)(6)** (File # 2848 dated June 4, 2009), **(b)(6)** (Fil # 3839 dated November 23, 2009) and **(b)(6)** (File # 4023 dated January 5, 2010).

c) Additionally, during the inspection, the investigator observed that Regulatory Affairs failed to review previous complaint history or FDA Maude (MDR) database to review previous related incidents for similarities or trends and update the complaint database system with analysis data as required.

The adequacy of your firm's response dated September 8, 2010, cannot be determined at this time. Your firm stated you were reviewing the training c the current Customer Service Staff and were providing additional training as needed. Additionally, the on-boarding process for new customer service staff was reviewed to ensure that new associates in the future have documented training in place prior to processing calls of this type. These activities were expected to be completed by October 15, 2010; however, your firm has not provided any evidence of implementation of these corrective actions.

Our inspection also revealed that your Invacare medical beds devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in tha your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i and 21 C.F.R. Part 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

Failure to report to the FDA no later than 30 calendar days after the day that you become aware of information, from any source, that reasonably suggests that a device that you market has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example: Two complaints that should have been reported to FDA as malfunction MDRs are Complaint #2850, dated June 3, 2009, *"Consumer alleged her control box on the bed caught fire"*, involving the Bariatric Bed, Model #BAR600IVC; and Complaint #4470, dated March 29, 2010, *"Head motor sparked and smoked during bed set up, then stopped working"* involving the Bariatric Bed, Model #BARPKGIVC-1633.

Your firm's response dated September 8, 2010, did not address this charge because it was not on the FDA 483 issued to you at the end of the inspection.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Ronnie E. Jackson, Director of Compliance, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions about the content of this letter please contact Mr. Jackson at (407) 475-4734.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,
/S/
Emma R. Singleton
Director, Florida District

Links on this page: